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Twenty-fifth day of June 2004

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ORAL APPLIANCE

This invention relates to an oral appliance.

More specifically this invention relates to an oral appliance which is capable of being user customised to suit the mouth or oral cavity of a patient or user. This invention also relates to a method of making this appliance using molding techniques.

This invention finds particular but not exclusive application as a mouthguard for use in sports and as an orthodontic appliance for use in correcting myofunctional and tooth alignment problems.

While customised orthodontic appliances are known, these are relatively costly. This is because each appliance has to be made individually and separately in a laboratory after a mould or impression of the patient or user's mouth has been obtained. Naturally it would be advantageous if an appliance could be devised which could be mass produced and which was also capable of being adjusted to fit the dimensions of a particular patient's mouth on the spot while the patient was sitting in a dental chair.

Similarly, while customised sports mouthguards are the guards of choice amongst sports people, they are expensive. While mass produced sports mouthguards are known, they have some real limitations. Specifically, because of a wide range of user mouth sizes and shapes, they often do not fit snugly into the mouth of the user. It would also therefore be advantageous if an appliance could be devised which was mass produced and which was also capable of being customised to fit snugly into a user's mouth by the end user without dental assistance.

According to one aspect of this invention there is provided an oral appliance for placing in the mouth of a user, comprising a base member having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member

defining at least one channel within which an upper or lower row of teeth of a user can be received, a teeth engaging element, associated with each channel, being made of a material able to be user conformed or user molded to suit the individual mouth of the user, and shock absorption means associated with the base member and/or the teeth engaging element for absorbing impact shock.

The base member provides a degree of rigidity and impact resistance to the mouthguard, thereby assisting in prevention of concussion resulting from primarily blows to the lower jaw, whilst the teeth engaging element provides a snug, comfortable fit. The shock absorbers enable the full shock of an impact to be substantially absorbed by the mouthguard instead of the full force being transmitted to the jaw, specifically the temporo-mandibular joints and on into the skull.

The base member is preferably more rigid than the teeth engaging element.

The shock absorption means preferably comprise one or more pre-designated compressible areas associated with the base member and/or the teeth engaging element.

In a preferred embodiment the shock absorption means comprise one or more spacings arranged in a body of the base member and/or a body of the teeth engaging element, whereby the shock absorbers may take the form one or more open or closed air channels arranged in the base member. These air channels may extend from an outer face of the base member, through the body thereof to an inner face of the base member.

Preferably the shock absorption means take the form of open channels arranged in or near terminal ends of the generally U shaped form of the base member and/or at least one open channel arranged in a front section of the base member extending therebetween.

Accordingly there is not only provided a material based impact absorption but also an additional 'spring air' system which provides shock absorption very much like the leaf springs in a motor vehicle, since the provision of the spacings provides a better absorption of impact than a completely solid material. As such a comfortable absorption of shock is effected and the mouthguard is loaded in a progressive manner. Increasing impact force does not lead to complete depression or collapse since the force required to compress the shock absorbers exponentially increases with deflection similar to a rising rate suspension.

The open channels have dimensions of height lying in the range of 0.5-10 mm, preferably 1.5-5mm and length lying in the range of 0.5-30mm.

The front open channel has a length lying in the range 2-10mm, preferably 4-8mm.

Preferably the open channels arranged in or near the terminal ends of the generally U shaped form of the base member, have a length of between 10-20mm.

In a preferred embodiment, the teeth engaging element is made of a continuous layer of thermoplastic material that encompasses the base member to firmly and securely mount the layer of thermoplastic material on the base member, whereby the layer of thermoplastic material may be provided with one or more openings which correspond with at least one or more of the open channels arranged in the base member.

Alternatively the outer covering can be closed over the openings to provide extra air pressure during deflection, since the EVA outer covering, if closed over the "air springs" increases air pressure during deflection.

The base member preferably comprises a rigid, non-thermoplastic material, which is not user conformable or moldable in boiling water, and most preferably comprises polyurethane, polypropylene, santoprine or combinations thereof.

The layer of thermoplastic material can be EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C. and the base is made out of a rigid plastic material.

The layer of thermoplastic material, e.g. EVA, may have a thickness of 1mm-4mm, preferably 1mm-3mm, e.g. about 2mm. EVA has a suitable level of pliability and formability when heated to its softening temperature.

The base member may be made of a plastics material, preferably being non-thermoplastic below about 100°C and having a degree of flexibility. Preferably the base member is substantially rigid at temperatures of 90°C-95°C.

While EVA is preferred for the teeth engaging elements, any thermoplastic having a suitable softening temperature may be used. Preferably the element is malleable at a temperature below 100°C, e.g. so that it can be softened by immersion in boiling water.

Thus the continuous layer also covers a region of the base member intermediate the upper and lower channels, e.g. the outer walls of the flanges, as well as the channels. The layer encases the base member to firmly and securely mount teeth engaging elements on the base member without delamination. This overcomes the problem of getting EVA to bond to the base member.

In this specification, the term "engaging" shall bear a broad meaning and shall not be interpreted to mean "retaining" or "latching engagement".

Thus the upper and lower teeth engaging elements are capable of being molded to suit the teeth and jaws of a particular user by being heated above their softening point, e.g. by being immersed in boiling, or boiled, water and then inserted into the mouth of the user. The formable thermoplastic teeth engaging elements can then be conformed to the dimensions and other characteristics of the teeth and jaw of the user. This provides a customised mouthguard or orthodontic positioning appliance without the need for time consuming moulds to be taken of a patient's mouth.

The temperature to which the elements must be heated must be reasonable bearing in mind that the appliance is to be placed in the mouth of a patient. It is also important that the thermoplastic does not have any other toxic or other undesirable properties.

Preferably the continuous layer of thermoplastic material covers substantially the entire surface area of the base member and the layer is permanently attached to the base member at the time of manufacture. It is to be understood however that this arrangement is not essential and that the layer may be continuous without covering the entire surface area of the base member.

Preferably, the oral appliance forms a single integral article.

It will be understood that other plastics which are sufficiently strong and rigid and which do not have thermoplastic properties in the appropriate temperature ranges may also be used for the base member.

Thus the base member is reasonably rigid while the teeth engaging elements are softer than the base member, whereby the base member may still have a degree of flexibility to adapt to the arch size of the user.

In order to improve the flexibility of the base member, this may comprise a pre-determined amount by weight of a material having greater flexibility than the rigid material. For example the rigid base member comprises 10% or less of a thermoplastic material, preferably EVA, and preferably comprises EVA lying in the range 4-8% by weight of the base member. The addition of EVA to the material comprising the base member not only improves the flexibility thereof, but also improves the adhesion of the base member to the teeth engaging element.

The layer of thermoplastic material forming the teeth engaging elements can have a thickness of 1mm – 3mm.

In order to provide increase stability the continuous layer of thermoplastics material preferably substantially covers the complete surface area of the base member.

The base member preferably has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element is receivable in the upper channel and a lower teeth engaging element is receivable in the lower channel.

A tongue tag can be formed on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use.

Furthermore the base member may be equipped with breathing apertures defined therein for facilitating breathing by a user when wearing the appliance.

In one preferred embodiment, the oral appliance is adapted for use as an orthodontic appliance. In another preferred embodiment, the appliance is suitable for use as a sports mouthguard.

A related aspect of the present invention relates to a method of manufacturing an oral appliance as described above, comprising the steps of molding a base member from rigid material in a first molding step in a first mould, arranging one or more shock absorbing spacings in the base member and removing the base member from the first mould and placing it in a second mould having a larger mould cavity and molding a continuous layer of thermoplastic material onto the base member to form upper and lower teeth engaging elements capable of being customised to suit the mouth of a user , the layer encasing the member to thereby firmly and securely mount the layer of thermoplastic material on the base member.

Preferably the layer of thermoplastic material is injection molded from EVA while it is locked in position in the second mould.

Thus, the oral appliance may be formed in a two step injection molding process. More specifically, the base member may be injection molded in a first die or mould and then when it has been formed it is removed from the first die and locked into a second die or mould where the layer encasing the member is injection molded. Thus the teeth engaging elements surround or enclose the base member to effect attachment to the base member.

Alternately a co-injection molding process can be used where similarly the base member is formed in the same mould. The second or subsequent injections follow and cover the entire base member with the layer of EVA. The result is the same, however the process does not require removal of the base member to another die.

The invention will now be further described with reference to the following figures wherein:

FIG. 1 is a front three dimensional view of an oral appliance in accordance with one embodiment of the invention;

FIG. 2 is a rear three dimensional view of the oral appliance of FIG. 1;

FIG. 3 is a part sectional side view of the appliance of FIG. 1;

FIG. 4 is a front three dimensional view of the base member of the appliance of FIG.1;

FIG. 5 is a rear three dimensional view of the base member of FIG. 4;

FIG. 6 is a front three dimensional view of an appliance in accordance with a second embodiment of the invention;

FIG. 7 is a rear three dimensional view of the appliance of FIG 6;

FIG. 8 is a part sectional side view of the appliance of FIG. 6;

FIG. 9 is a front three dimensional view of the base member of the appliance of FIG. 6;

FIG. 10 is a rear three dimensional view of the base member of FIG. 9;

FIG. 11 is a sectional side view of the base member of FIG. 9;

FIG. 12 is a perspective view of a base member for a mouthguard according to the present invention provided with a shock absorption system;

FIG. 13 is a rear view of the embodiment from FIG. 12;

FIG. 14 is a side elevation of the embodiment shown in FIG. 12 and FIG. 13;

FIG. 15 is a rear view of another embodiment of a base member according to the present invention for a mouthguard exhibiting 'air spring' shock absorbers;

FIG. 16 is an above view of the embodiment shown in FIG. 15;

FIG. 17 is a perspective view of another embodiment of an oral appliance according to the present invention, illustrating openings in the thermoplastic layer which correspond with the 'air spring' shock absorber openings in the base member, whereby a brace element is fitted around the front of the thermoplastic layer;

FIG. 18 is a side view of the embodiment shown in FIG. 17;

FIG. 19 is a rear view of the embodiment shown in FIG. 17 and FIG. 18;

FIG. 20 is a further, rear, perspective view of the embodiment shown in FIGS 17-19;

FIG. 21 is a further, front, perspective view of the embodiment shown in FIGS 17-20;

FIG. 22 is a further rear perspective view of a preferred embodiment of a double mouthguard, i.e. having teeth engaging elements for both the upper and lower rows of teeth;

FIG. 23 is a front view of the embodiment from FIG. 22;

FIG 24 is a side view of the embodiment as shown in FIG. 22 and FIG. 23;

FIG. 25 is a rear perspective view of a further preferred embodiment of a double mouthguard according to the present invention;

FIG. 26 is a front perspective view of a further preferred embodiment of the present invention illustrating an extension attached to a brace, to which extension a cord is attachable for affixing the mouthguard to a face guard or a sports helmet for example;

FIG. 27 is an above view of the embodiment from FIG. 26;

FIG. 28 is a below view of the embodiments from FIG. 26 and FIG. 27;

FIG. 29 is a rear view of the embodiments shown in FIGS. 26-28;

FIG. 30 is a side view of the embodiments shown in FIGS. 26-29;

FIG. 31 is a front view of the embodiments shown in FIGS. 26-30;

FIGS. 32-37 show a further preferred embodiment of the mouthguard according to the present invention; and

FIG. 38 shows a view of another embodiment.

In FIGS. 1 to 5 reference numeral 1 refers generally to an appliance in accordance with the invention.

The appliance 1 comprises broadly a base member 2 and two teeth engaging elements 3 and 4.

The base member 2 has a broadly U-shaped configuration sized to complement the general U-shape of the jaw of a user when viewed in plan view. The base member 2 has a central web 5 and inner and outer flanges 6 and 7 projecting both upwardly and downwardly from both the inner and outer edges of the web 5.

The web 5 and flanges 6 and 7 collectively define upper and lower channels 10 and 11 within which respectively the upper and lower teeth engaging elements 3 and 4 are positioned.

The base member 2 is made of a substantially rigid plastic material having an appropriate mechanical strength. Polypropylyne, polyurethane and santoprine have been found to be very suitable although other plastics may also be used.

Each of the elements 3, 4 is made of a thermoplastic material which in the illustrated embodiments is EVA. The EVA softens at 90 to 95°C and thus can be softened by placing in boiling water.

Each of the tooth engaging elements 3 and 4 also has a broadly U-shaped configuration when viewed in plan view. This complements the general shape of the base member 2. Each element 3, 4 also has a broadly U-shaped cross sectional

configuration with a bottom wall 15 and two side walls 16 and 17. The shape and width of the channels defined in the base member 2 and elements 3 and 4 have been specifically designed so as to enable the appliance to accommodate widely varying jaw widths and thereby be capable of being fitted to a large number of patients. The appliance also includes a notch or cut-out 35 in the upper surface of the outer flange 7. The notch 35 allows inward or outward adjustment of the arms of the U-shaped member without causing distortion of the appliance 10. This assists in fitting a single size appliance to patients with widely different arch sizes.

In the illustrated embodiment, the layer of EVA forming the elements 3, 4 extends continuously across the full surface area of the base member including the outer surface of the flanges 6 and 7 and thus covers more than just the U-shaped channels of the base member 2. The reason for applying the layer of thermoplastic material across the entire surface area of the base member is to mount or attach the EVA layer to the base member which is made of polyurethane, polypropylene or santoprine.

EVA does not bond naturally to the base member when it is molded onto the base member and thus a way has to be found of securing it to the base member. This is accomplished by mechanically encasing or enclosing the base member within the layer of EVA. The inability of EVA to bond to the plastic base member is a major problem to be overcome in manufacturing these appliances.

The appliance has a tongue tag 25 for positioning the tongue in an exact central position.

The tongue tag is preferably provided with one or more notch cut outs that also allow inward and outward adjustment of the arms of the U shaped member without causing distortion of the appliance.

The appliance also has a plurality of holes 30 defined therein that permit mouth breathing.

A further feature of the appliance is that the web of the base member 2 tapers outwardly from the leading edge thereof up to a point thickening the web, and then tapers inwardly after that to the rear end progressively thinning the web. Thus, the web has a cross sectional configuration so as to substantially occupy the space between the teeth of upper and lower jaws of the user. This configuration which is clearly illustrated in the applicant's prior applications may generally be described as an asymmetrical aerofoil shape having a curved surface on the lower side. The web may have a thickness of about 6mm at its thickest point.

This supports the jaw of a user and encourages the lower jaw to assume its anatomically correct position relative to the upper jaw. This is believed to cause a relaxation of muscles in the head and the neck. This configuration of the web of the base member opens the "bite" and holds the jaw in a more down and forward position. In this position, the jaw is more resistant to injury. This jaw position is understood to enhance athlete performance. Further, the thickening of the web naturally also strengthens the appliance.

The appliance 1 can be made in a two-step injection molding process. The base member 2 is injection molded in a first die from polyurethane. The base member 2 is then switched to a second die having a larger cavity and the layer of EVA, including the teeth engaging members 3, 4, is then molded onto the base member.
The injection molding process comprises broadly the injection of a viscous resin from a heated cylinder into the die by means of a plunger or injector. The die is cooled by cooling means, e.g. chilled cooling water, causing the resin to cure and harden. The molded article can then be removed from the die. The injection molding techniques used to form the appliance would be well known to a person skilled in the art and do not form part of the invention. Therefore, they will not be described in further detail.

In use, the mouthguard may be in one example application be fitted by a dentist in a dental surgery. In other applications, the guard may be fitted by a user. This is done by heating the appliance up to 90°C by soaking it in boiling water. When this occurs

the base member remains rigid while the elements 3, 4 soften making them suitable for being customised to the individual tooth and jaw shape of a user. The appliance is then placed in position in the mouth of a user and the elements 3, 4 conform to the user's teeth and jaw and then harden in this position.

In a second embodiment of the invention illustrated in Figs. 5 to 11, the appliance is used for orthodontic treatment. The orthodontic appliance is the same as that illustrated in FIGS. 1 to 5 with the exception that it does not have breathing holes, e.g. for mouth breathing, and the base element 2 is thinner, e.g. having an approximate thickness of 2mm to 4mm, because it does not have the same requirements of mechanical strength as the sports guard. The orthodontic appliance is used for myofunctional training and tooth realignment. Myofunctional training is a clinical procedure which is designed to correct bad oral habits, e.g. tongue thrusting, mouth breathing, incorrect swallowing and the like.

In the embodiments illustrated in figures 1-11, 'air spring' shock absorbers are not shown.

Figures 12-21 show embodiments of the present invention equipped with 'air spring' shock absorbers, for absorbing impact shock.

These embodiments are provided with spacings 50, arranged in the rear flanges of the base member and a front spacing 52, arranged at the front of the appliance below the front, upper notch. These spacings provide compressible areas able to absorb impact shock.

A preferred embodiment of the oval appliance shown in figures 17-21 is provided with a brace, 54, attached to, and extending around, the teeth engaging element.

The brace is preferably made of thermoplastic rubber and assists lower jaw location during molding. The rear part of the brace locates and centralizes the lower jaw laterally and the front part of the brace allows positioning of the lower jaw (by

putting the front teeth immediately behind the closed front brace). On fitting of the appliance according to the present invention, the user then bites together on the heated EVA. This optimizes the lower jaw position for the MORA effect, as described in previous patent.

Furthermore, additional protection is provided by these elements of the closed brace for the lower front teeth without the requirement of a double mouthguard. The brace also provides adequate breathing space.

The rear part of the brace when molded, gives added protection from side blows by holding the lower jaw braced from lateral movement. This provides similar features to a double mouthguard but with less bulk and much more freedom of movement whilst still maintaining optimum breathing, speaking and lower front tooth and jaw protection.

It will be clear that the embodiments shown in figures 12-37 are variations on the embodiment shown in figures 1-11 whereby reference to corresponding technical features as shown in figures 1-11 have not been made in figures 12-37.

Figures 22-25 show preferred embodiments of a double mouthguard according to the present invention whereby the air springs extend through both the base member and the teeth engaging elements, and decrease in length from the front of the mouthguard to the rear of the mouthguard.

Most preferably, embodiments of the present invention equipped with the 'spring air' shock absorbers have base members with a degree of flexibility provided by adding a pre-determined amount of flexible material, particularly EVA, to the base material.

In use the appliance is initially fitted by a dentist or orthodontist in a dental surgery. The shape of the elements 3, 4 prior to use corresponds broadly to an ideal positioning or "bite" of a patients teeth. To enable the elements 3, 4 to be tailored to

a patients specific teeth, the elements 3, 4 are dipped into boiling, or boiled, water to soften the elements and then inserted into a patients mouth to mould them to the specific contours of a patient's mouth.

The EVA material from which the elements 3, 4 are formed has a memory so that it reverts to its original shape when reheated. It reverts partly to its original shape when heated to 60 to 65°C and fully to its original shape when heated above 90°C.

The memory properties of the EVA enable the elements 3, 4 to be used to progressively correct misalignment of a patients teeth. For example at spaced time intervals, the dentist will typically place the appliance into water at a temperature of 60 - 65°C which causes the elements 3, 4 to partly revert to their original shape. The slightly altered shape brought about by this remolding causes the appliance to apply pressure to the teeth of a user to correct misalignment. This can be done several times until the patients teeth take up the correct position or the ideal "bite" position.

When the teeth are in the correct position the appliance can be placed into water at 90 - 95°C which causes it to revert fully to its original position. The appliance can then be used as a retaining device for retaining the teeth in the correct position and also for carrying out myofunctional training.

An advantage of the appliance described above is that it enables industrially manufactured mouthguards to be customised to a user's mouth very easily and simply, e.g. in a dentist's chair or by a user. A further advantage is that the appliance can be applied equally to orthodontic and sports guard applications. A yet further advantage of the appliance is that it effectively attaches the EVA elements to the base member.

The sports mouthguard described above is very effective because it protects both upper and lower teeth and also the jaw joints. The orthodontic appliance provides an inexpensive device for correcting myofunctional and tooth alignment problems.

It will of course be realised that the above has been given only by way of illustrative example of the invention and that all such modifications and variations thereto as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of the invention as is herein set forth.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An oral appliance for placing in a mouth of a user, the appliance including:

- a base member having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received,

- a teeth engaging element, associated with each channel, being made of a material able to be user conformed or user moulded to suit the individual mouth of the user, and;

- shock absorption means associated with the base member and/or the teeth engaging element for absorbing impact shock.

2. Oral appliance according to claim 1, wherein the base member has a greater rigidity than the teeth engaging element.

3. Oral appliance according to claim 1 or claim 2, wherein the shock absorption means comprise one or more pre-designated compressible areas associated with the base member and/or the teeth engaging element.

4. Oral appliance according to any of the preceding claims, wherein the shock absorption means comprise one or more spacings arranged in a body of the base member and/or a body of the teeth engaging element.

5. Oral appliance according to any of the preceding claims, wherein the shock absorption means comprise one or more open or closed air channels.

6. Oral appliance according to any of the preceding claims wherein the shock absorption means are arranged in the base member.

7. Oral appliance according to claim 5 or claim 6, wherein the air channels extend from an outer face of the base member, through the body thereof to an inner face of the base member.

8. Oral appliance according to claim 7 wherein the shock absorption means take the form of open channels arranged in or near terminal ends of the generally U shaped form of the base member and/or at least one open channel arranged in a front section of the base member extending therebetween.

9. Oral appliance according to claim 8 wherein the open channels have dimensions of height lying in the range of 0.5-10 mm, preferably 1.5-5mm and length lying in the range of 0.5-30mm.

10. Oral appliance according to claim 9 wherein the front open channel has a length lying in the range 2-10mm, preferably 4-8mm.

11. Oral appliance according to claim 9 or claim 10, wherein the open channels arranged in or near the terminal ends of the generally U shaped form of the base member, have a length of between 10-20mm.

12. Oral appliance according to any of the preceding claims further comprising locating means, for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance.

13. Oral appliance according to claim 12, wherein the locating means comprise a brace arranged externally on the teeth engaging element.

14. Oral appliance according to claim 12 or claim 13, wherein the brace comprises rubber, preferably thermoplastic rubber.

15. Oral appliance according to any of the preceding claims wherein the teeth engaging element is made of a continuous layer of thermoplastic material that encompasses the base member to firmly and securely mount the layer of thermoplastic material on the base member.

16. Oral appliance according to claim 15 wherein the layer of thermoplastic material is provided with one or more openings which correspond with at least one or more of the open channels arranged in the base member.

17. Oral appliance according to any of the preceding claims wherein the base member comprises rigid material, which is not user conformable or mouldable in boiling water.

18. Oral appliance according to any of the preceding wherein the layer of thermoplastic material is EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C and the base is made out of a plastic material of greater rigidity than the thermoplastic layer.

19. Oral appliance according to claim 18 wherein the base member comprises a non-thermoplastic material.

20. Oral appliance according to claim 19, wherein the base member comprises polyurethane, polypropylene, santoprine or combinations thereof.

21. Oral appliance according to any of the claims 17-20,wherein the base member comprises a pre-determined amount by weight of a material having greater flexibility than the rigid material.

22. Oral appliance according to claim 21 wherein the base member comprises 10% or less of a thermoplastic material, preferably EVA, and preferably comprises EVA lying in the range 4-8% by weight of the base member.

23. Oral appliance according to any one of the preceding claims, wherein the layer of thermoplastic material forming the teeth engaging elements has a thickness of 1mm – 3mm.

24. Oral appliance according to any one of the preceding claims wherein the continuous layer of thermoplastics material substantially covers the complete surface area of the base member.

25. Oral appliance according to any of the preceding claims wherein the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element is receivable in the upper channel and a lower teeth engaging element is receivable in the lower channel.

26. Oral appliance according to claim 25 wherein a tongue tag is formed on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use, and/or allowing better adaptation to varying arch sizes.

27. Oral appliance according to any one of the preceding claims, wherein the base member has breathing apertures defined therein for facilitating breathing by a user when wearing the appliance.

28. A method of manufacturing an oral appliances for placing in the mouth of a user, the method including the steps of:

molding a base member from plastic material in a first molding step in a first mould, the member having a generally U-shaped form corresponding to the outline of the jaw of a user and inner and outer flanges interconnected by a web which define at least one of upper and lower channels within which the corresponding rows of teeth of a user are received;

arranging one or more spacings in the base member and;

optionally removing the base member from the first mould and placing it in a second mould having a larger mould cavity and moulding a continuous layer of thermoplastic material onto the base member to form upper and lower teeth engaging elements capable of being customised to suit the mouth of a user , the layer encasing the member to thereby firmly and securely mount the layer of thermoplastic material on the base member, or co-injection in the same mould.

29. A method according to claim 28 wherein the continuous layer of thermoplastic material is molded substantially fully across the surface area of the base member in said second molding step, wherein optionally, the second molding step is also carried out in the first mould, preferably in a co-injection step.

30. A method according to claims 28 or 29 wherein the base member is injection molded from polyurethane, polyethylene, polypropylene or santoprine.

31. A method according to any one of claims 28-30, wherein the layer of thermoplastic material is injection molded from EVA while it is locked in position in the second mould.

32. Base member for an oral appliance for placing in a mouth of a user, having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received, the base member further comprising shock absorbing means taking the form of pre-designated compressible sections in order to substantially absorb impact shock.

33. Base member according to claim 32 comprising a first material, preferably being polyurethane and a second material, preferably being EVA, wherein the weight percentage of EVA in the base member preferably lies in the range 0.5-10% and is more preferably in the range 4-8%.

34. Base member according to claim 29 or claim 30 being at least semi-flexible and non-thermoplastic.

35. A moldable teeth engaging element for co-operation with a base member according to any of the claims 32-34 for an oral appliance, the element being made of a material able to be user conformed or user molded to suit the individual mouth of the user, optionally provided with locating means for correctly locating and positioning the jaws in the teeth engaging element.

36. A method of fitting an oral appliance, as described in any of the claims 1-27, comprising the step of immersing the oral appliance in water having a temperature sufficiently high to make the teeth engaging element moldable;

- inserting the appliance into a user's mouth;

- biting into the teeth engaging element to mould the teeth engaging element to the form of the user's jaw, and thereafter allowing the teeth engaging element to harden.

38. Method for protecting teeth from impact shock comprising the step of inserting an oral appliance, fitted according to claim 36, into a user's mouth before partaking of any activity whereby use of a mouthguard is desirable.

DATED THIS THIRTEENTH DAY OF JUNE 2003

CHRISTOPHER JOHN FARRELL

BY

PIZZEYS PATENT AND TRADE MARK ATTORNEYS

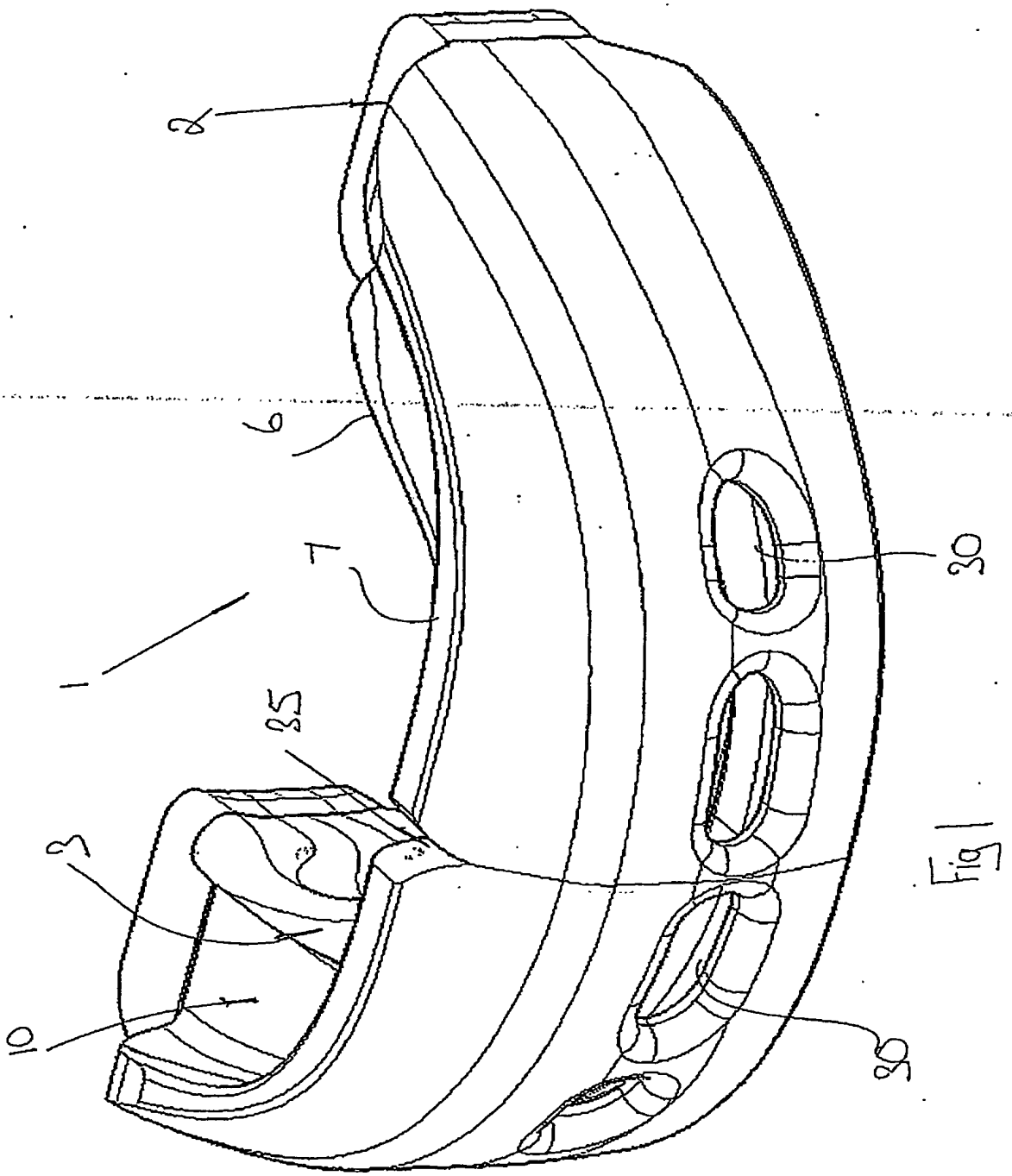


Fig 1

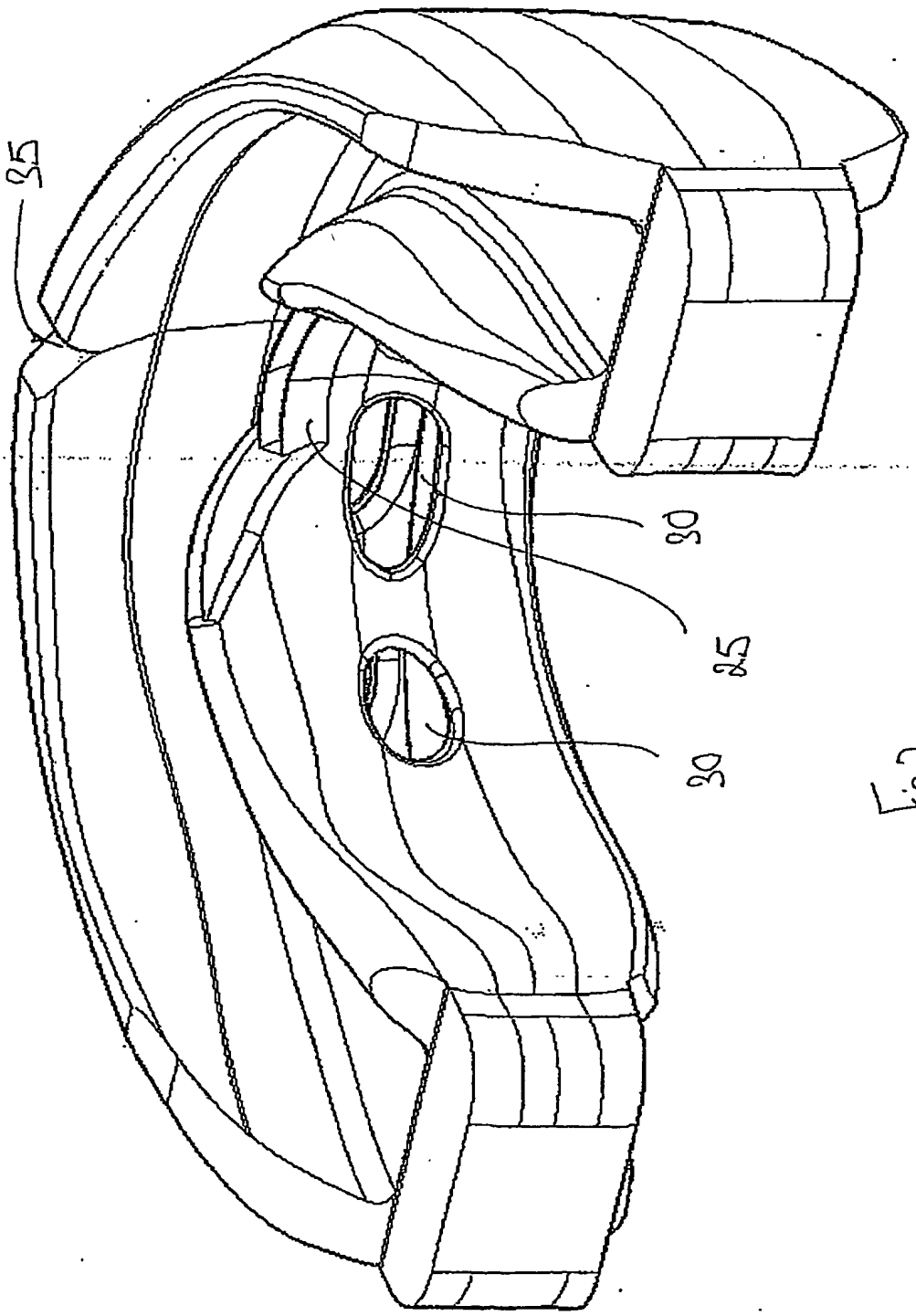


Fig 2

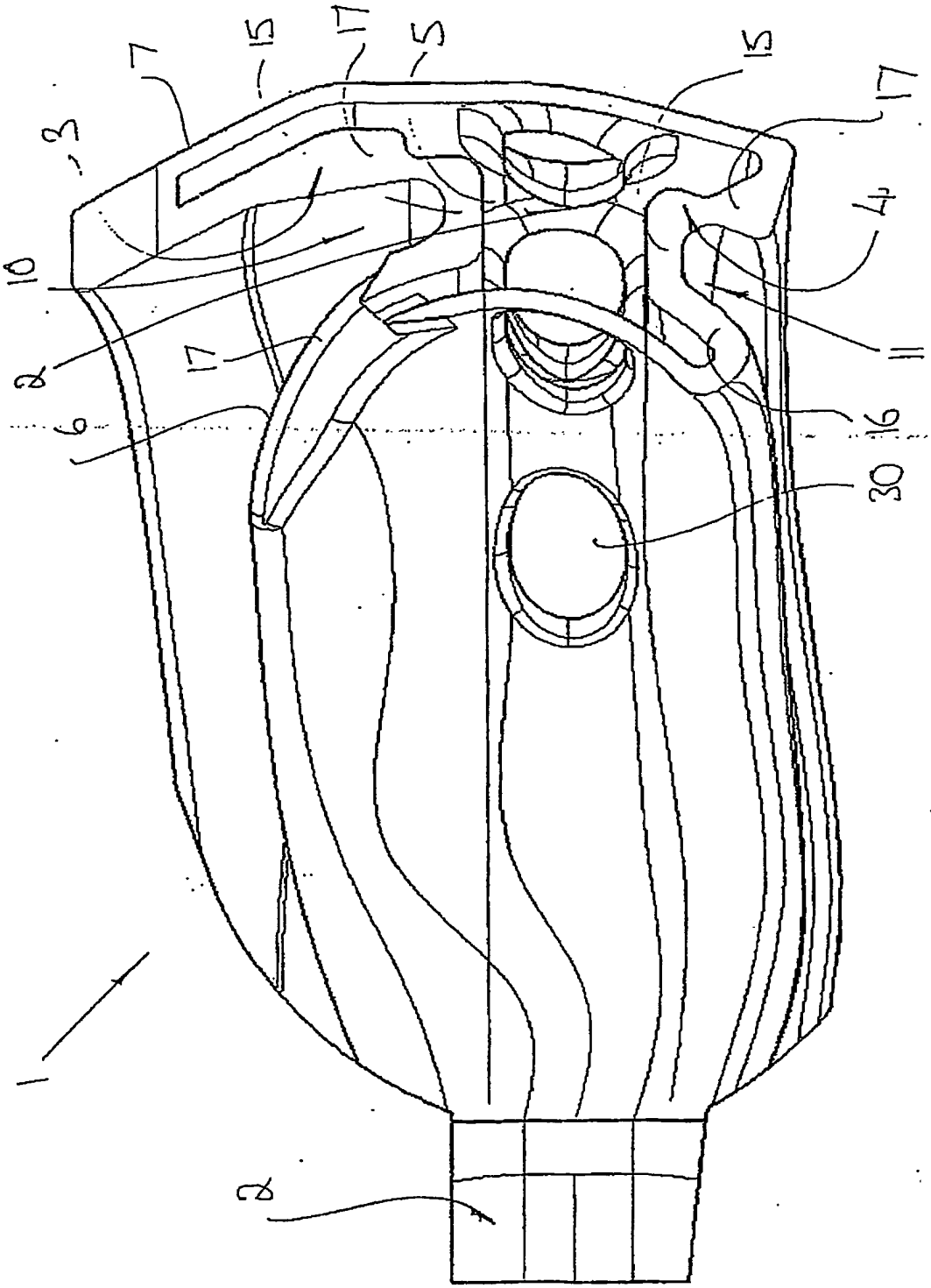


Fig3

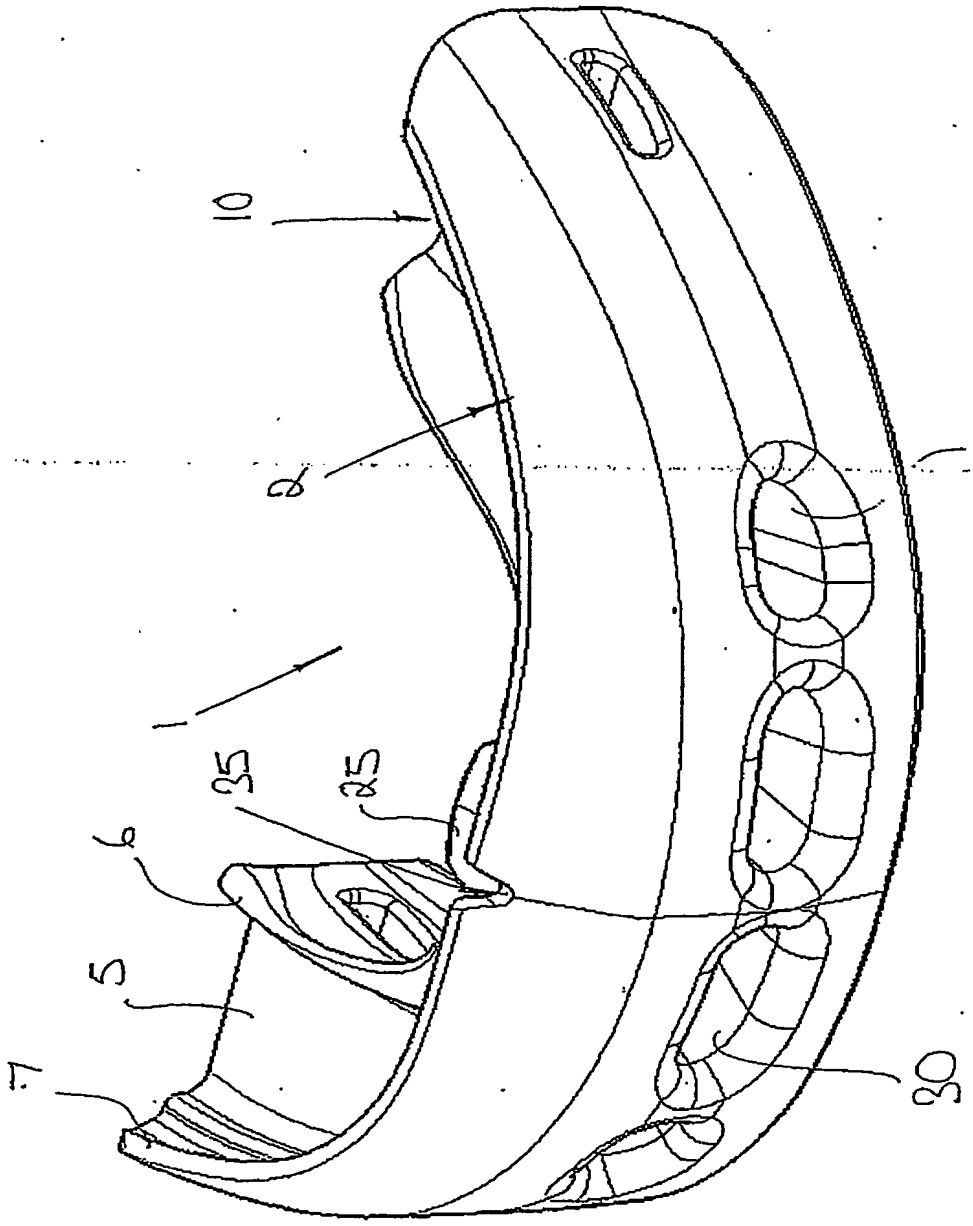


Fig 4

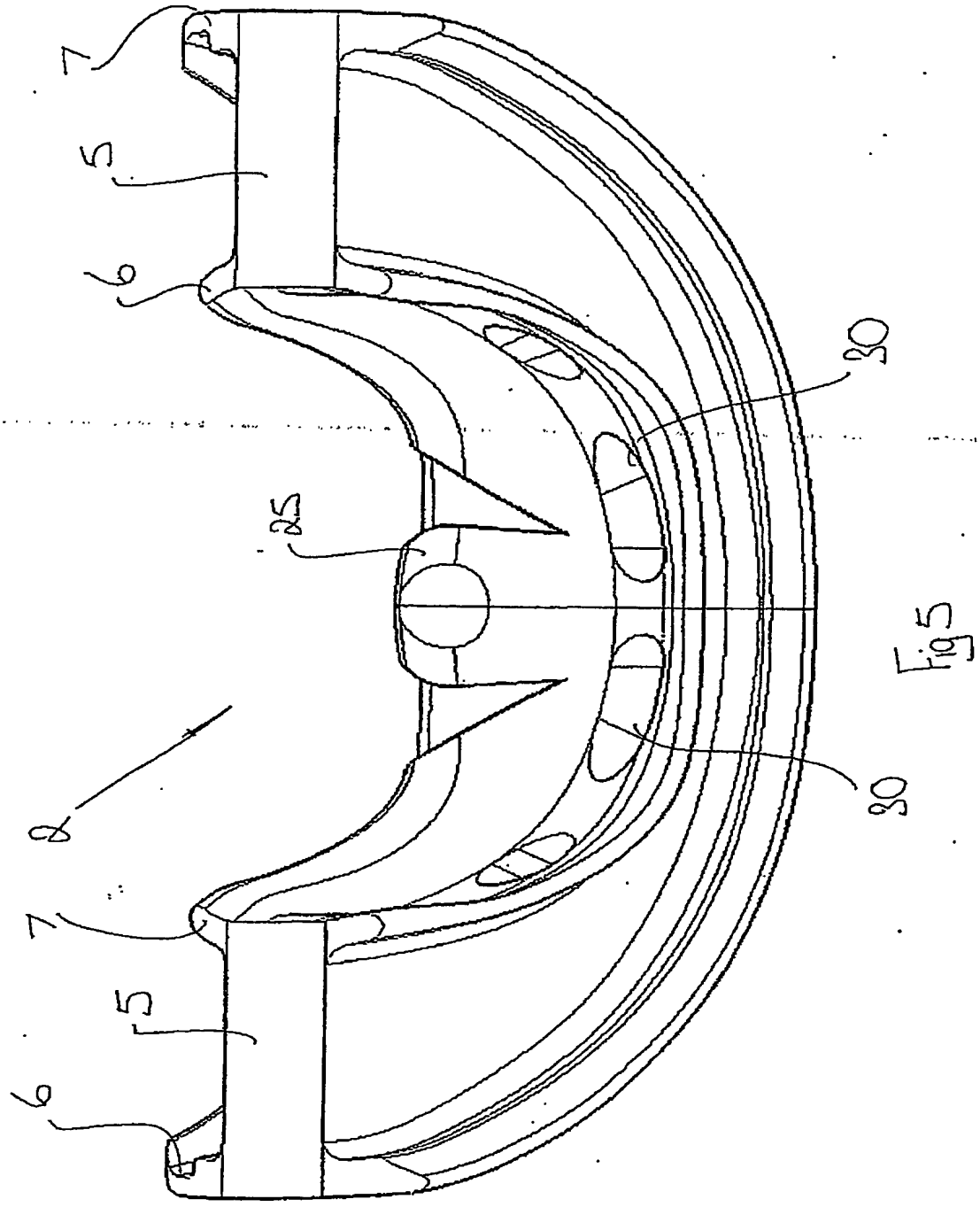


Fig 5

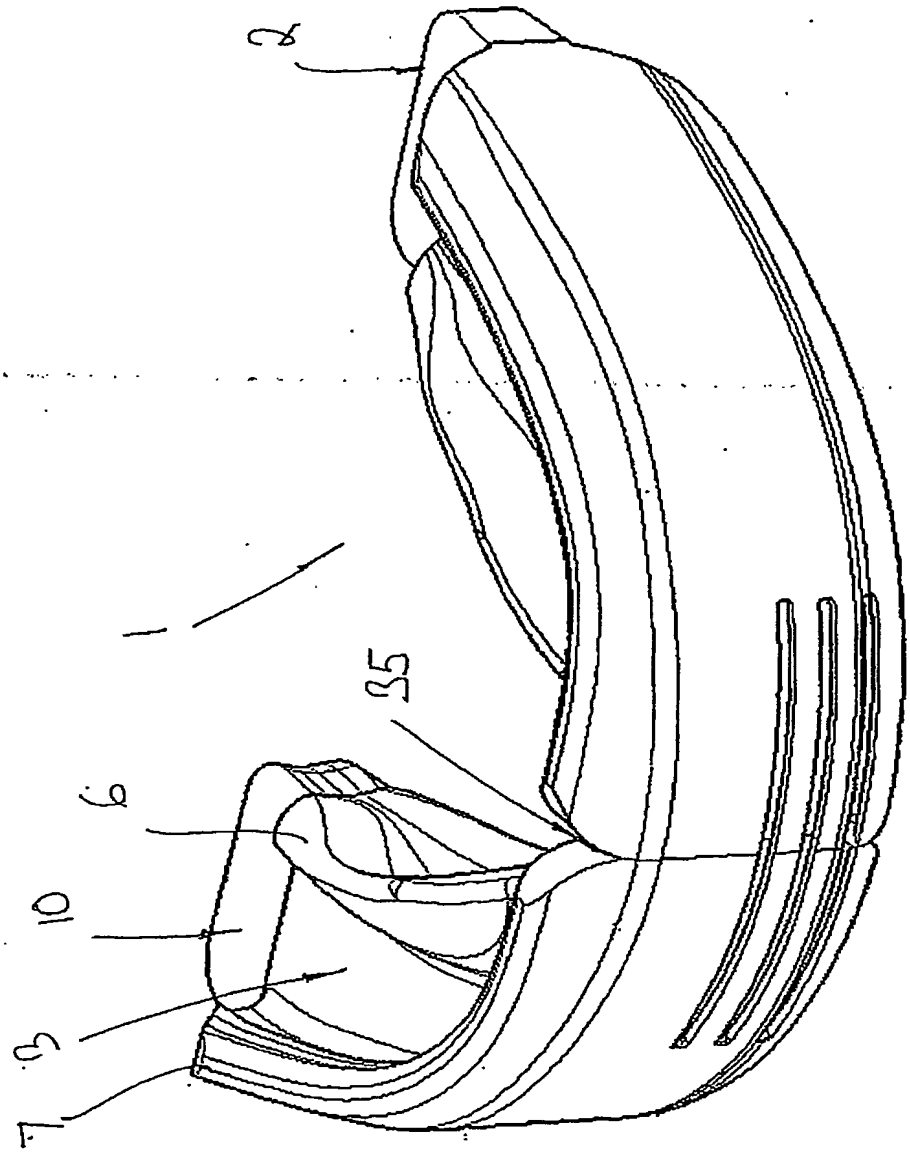


Fig 6

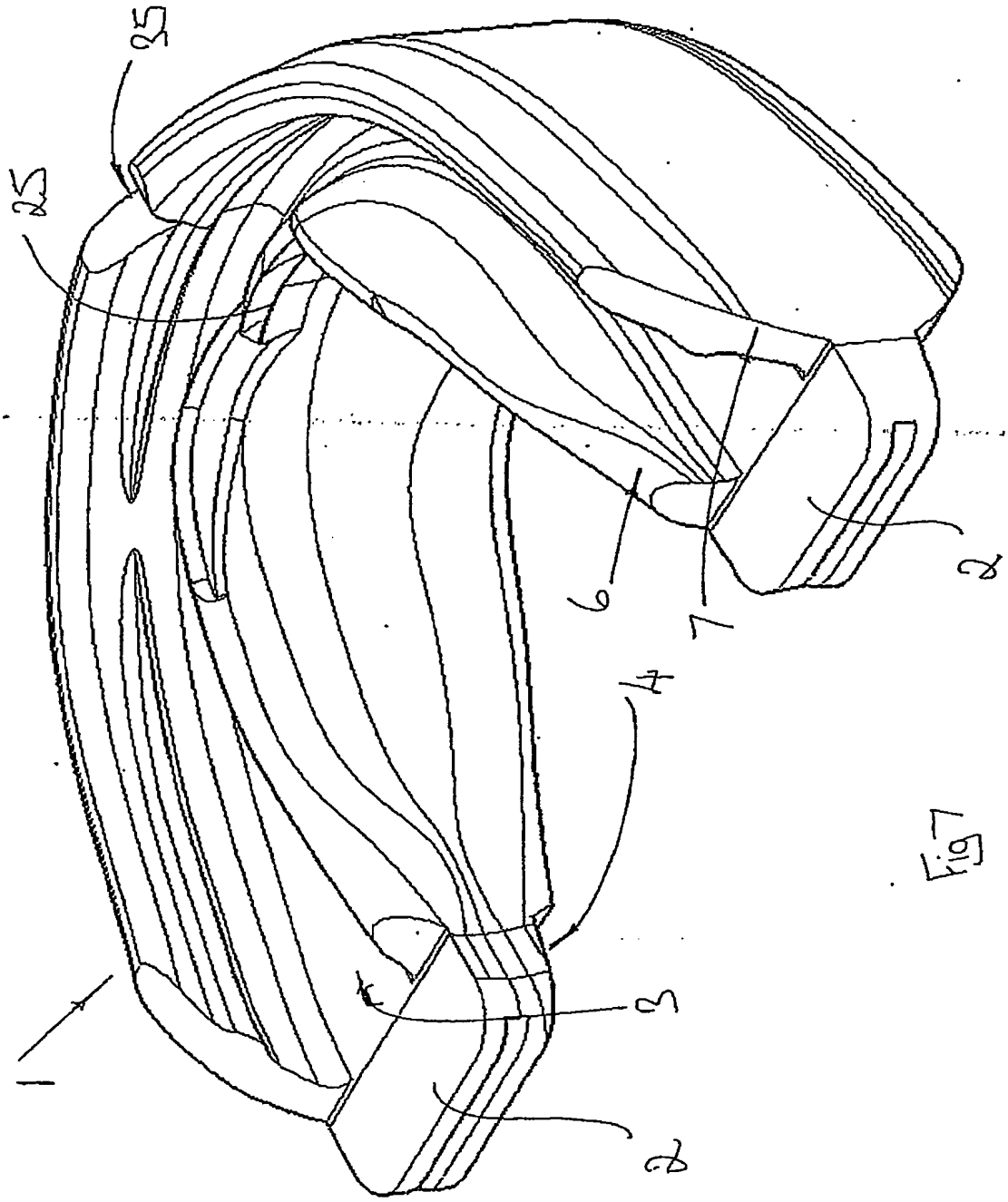


Fig 7

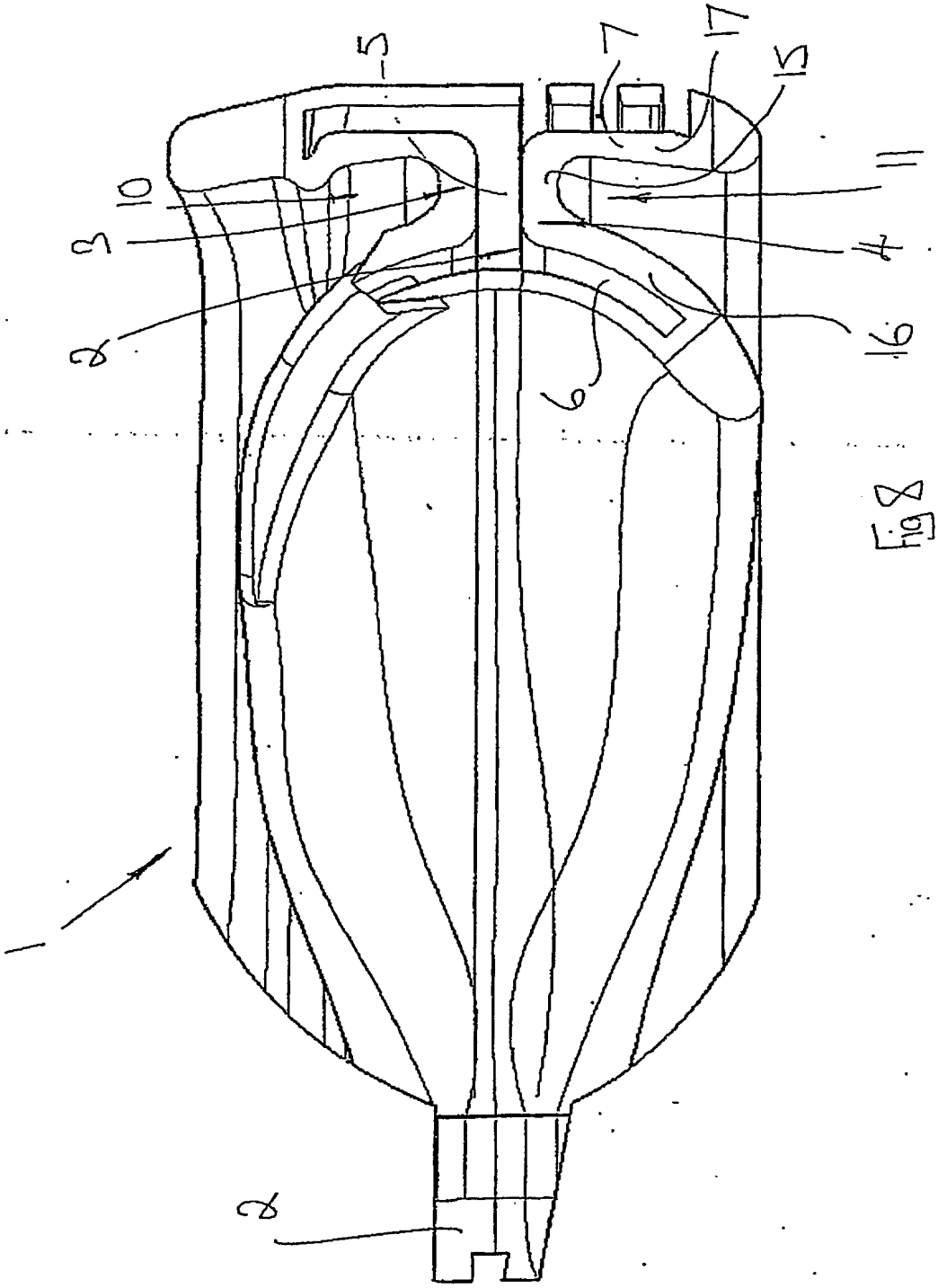


Fig 8

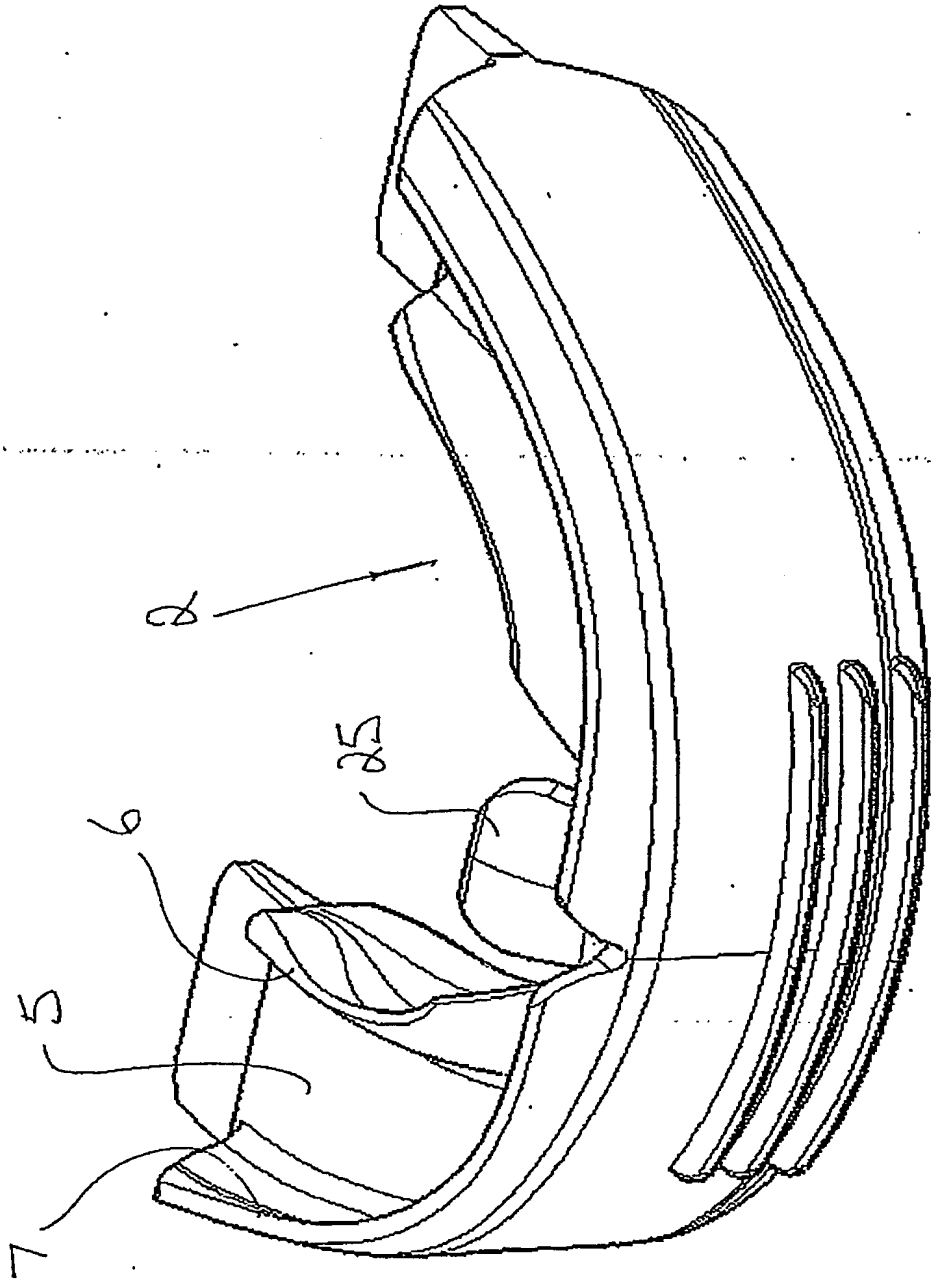


Fig 9

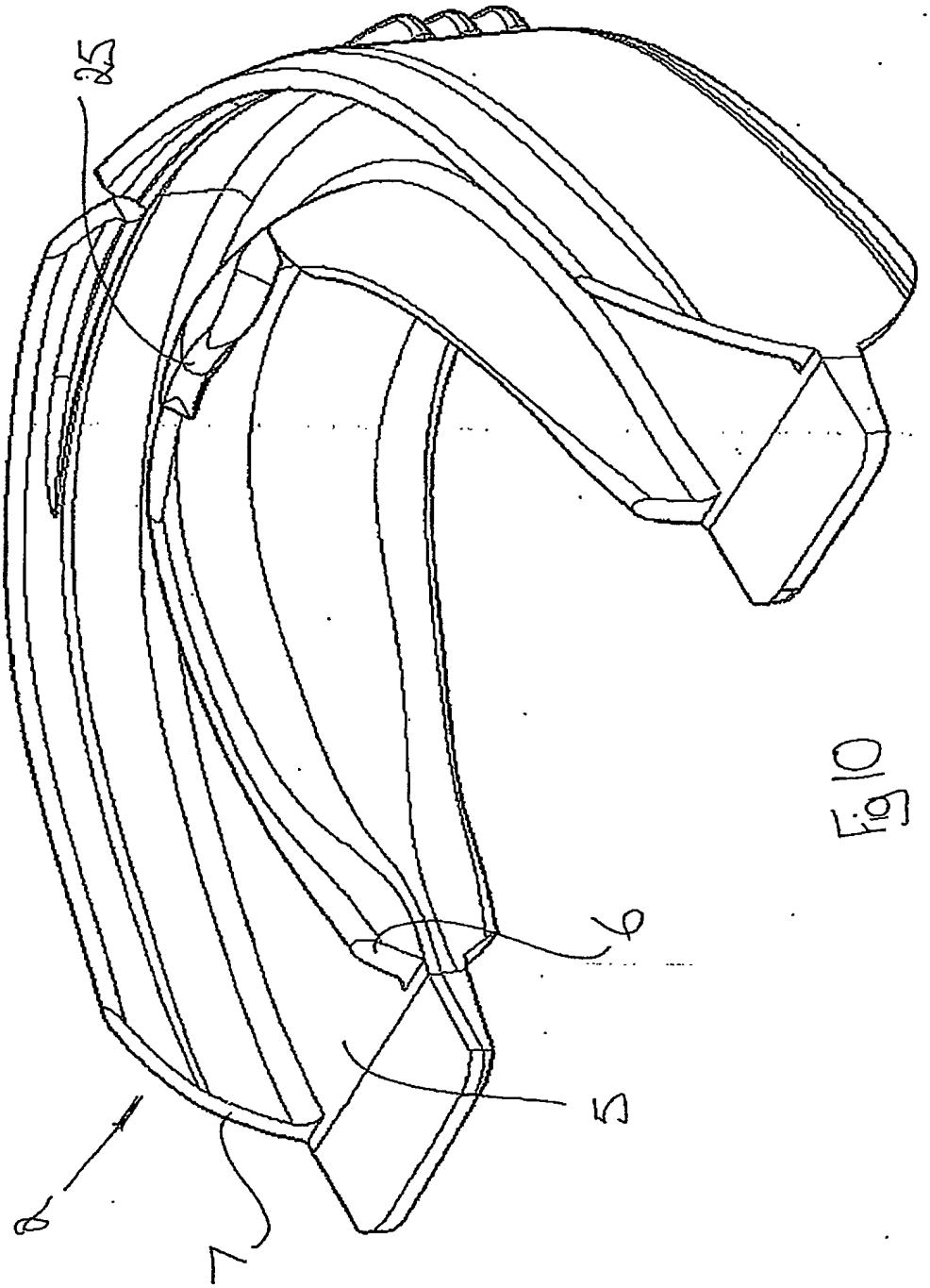


Fig 10

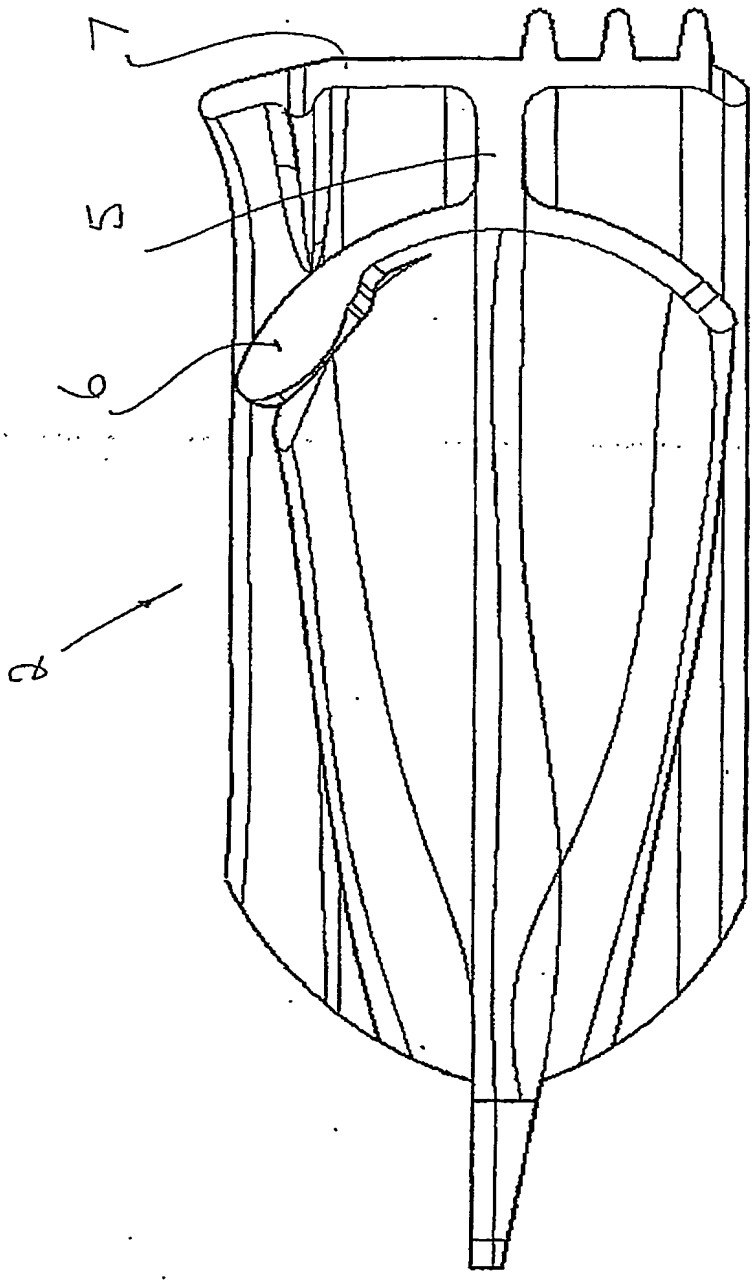


Fig 11

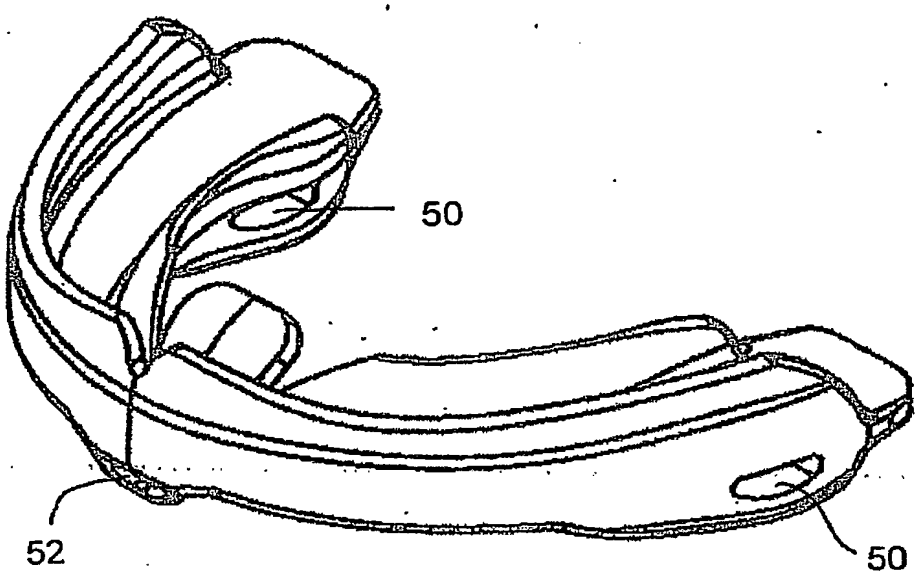


FIG. 12

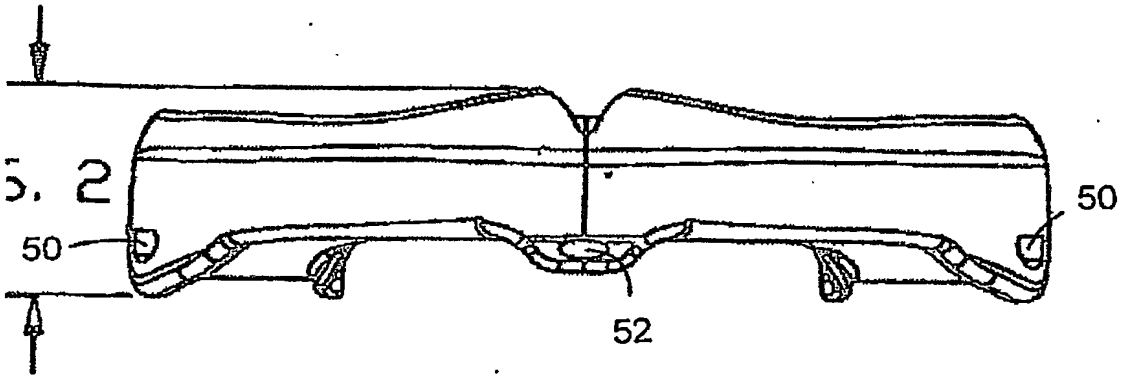


FIG. 13

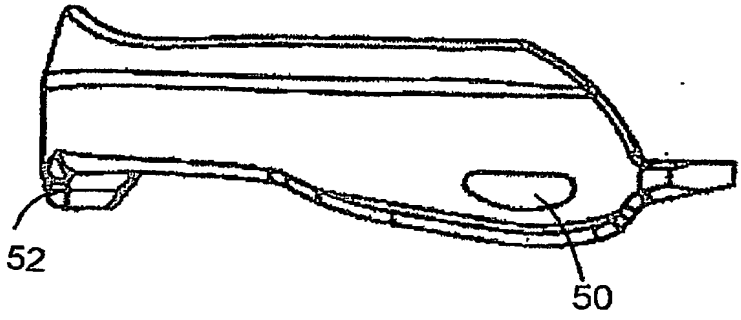
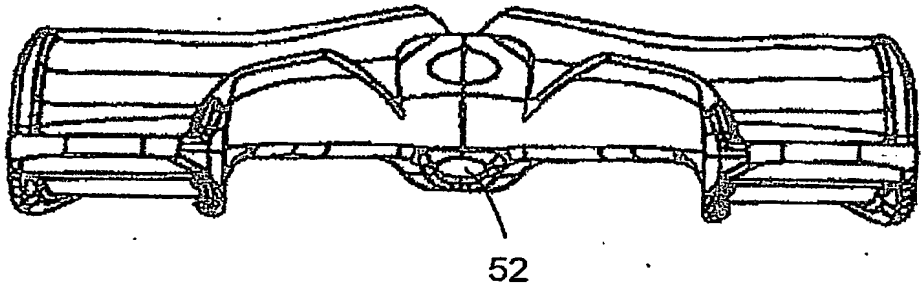


FIG. 14



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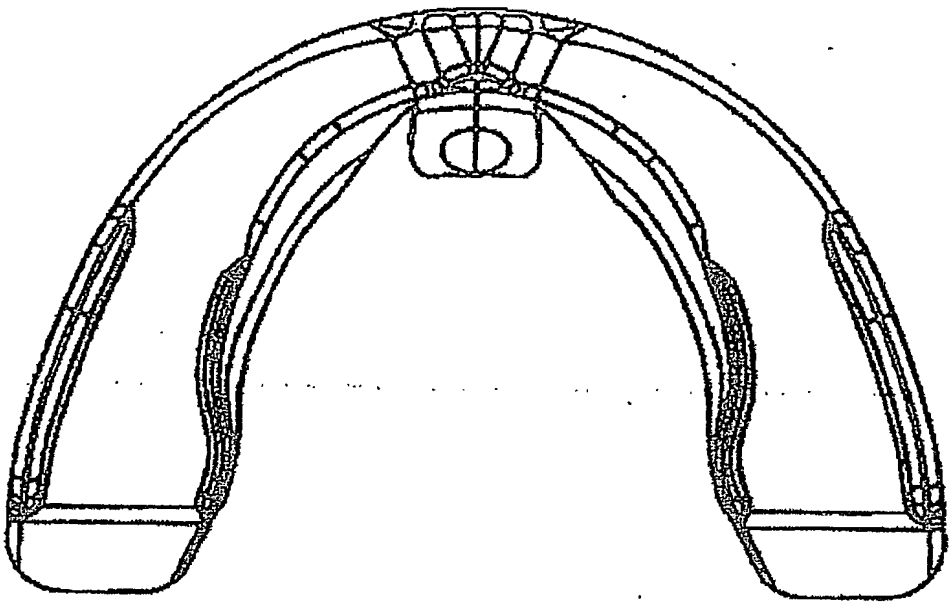


FIG. 16

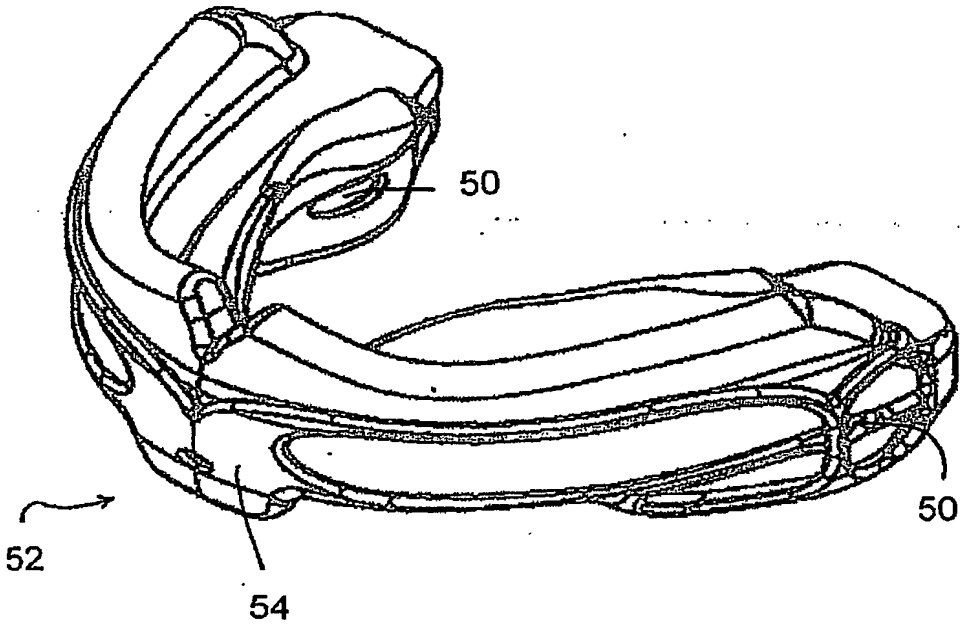


FIG. 17

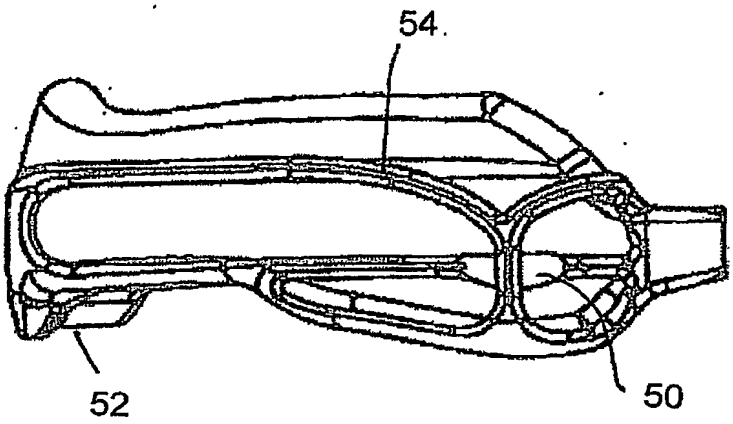


FIG. 18

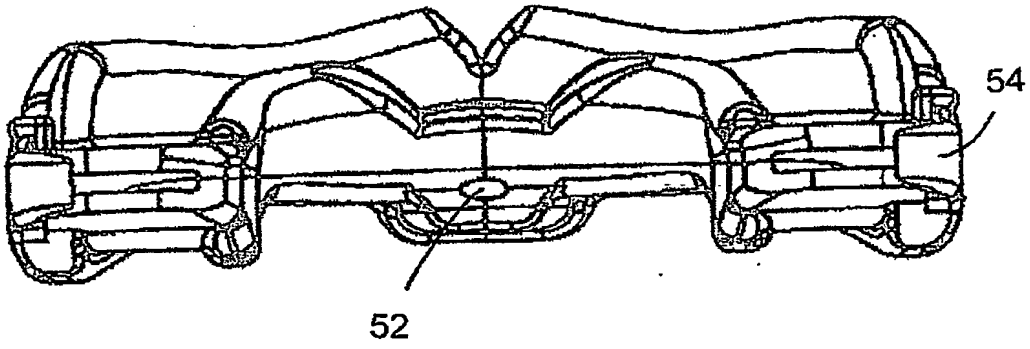


FIG. 19

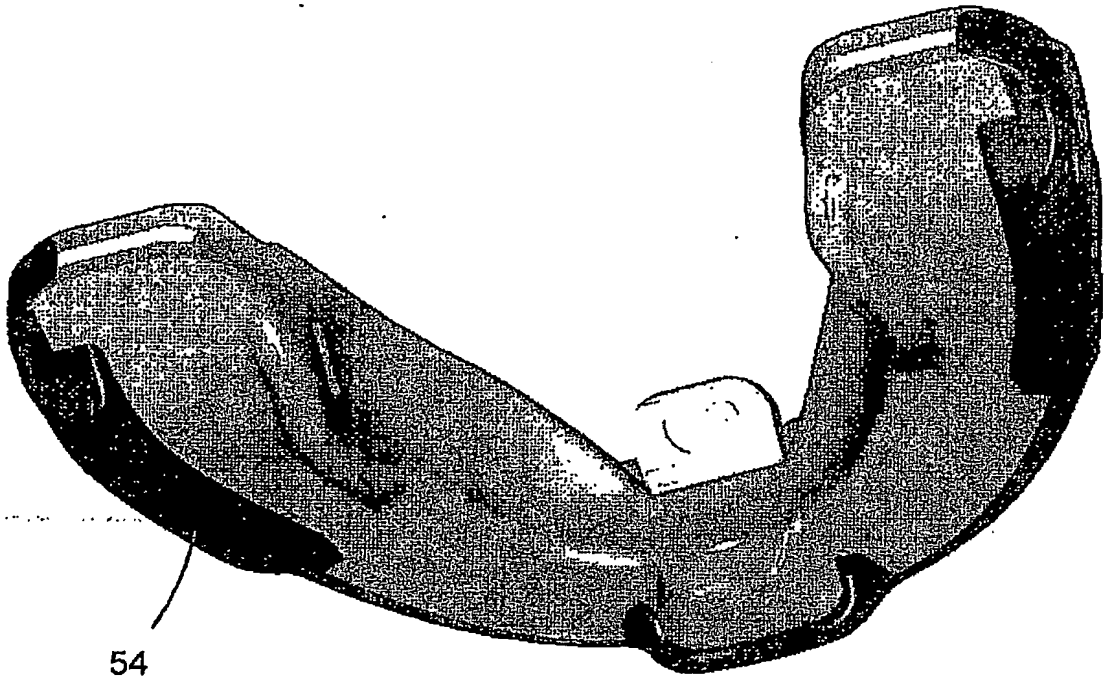


FIG. 20

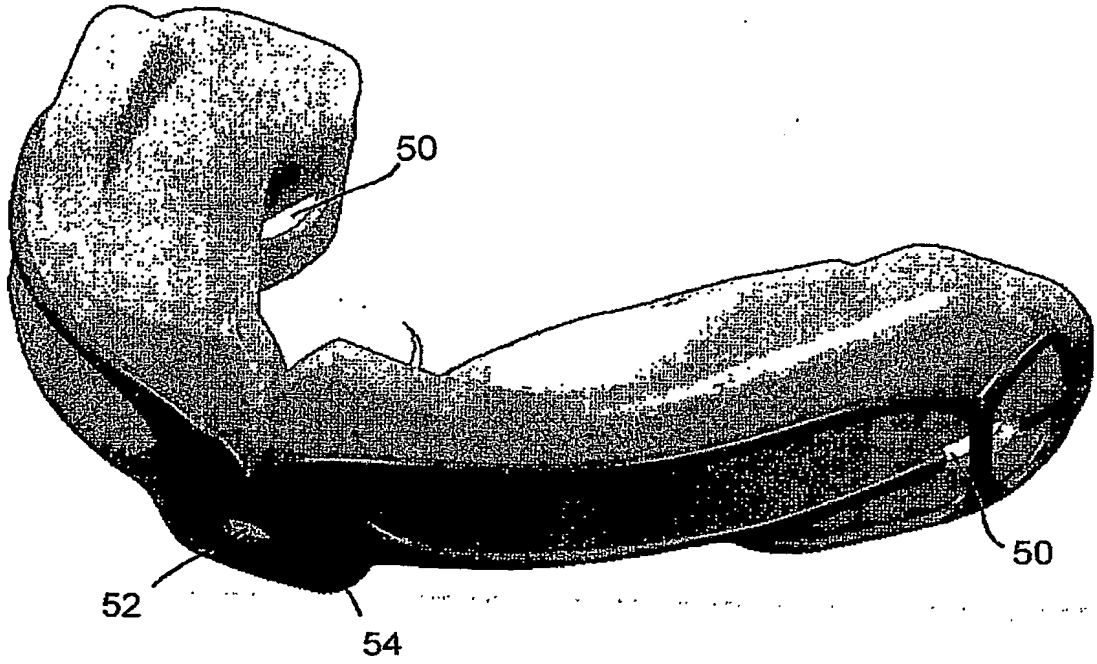


FIG. 21

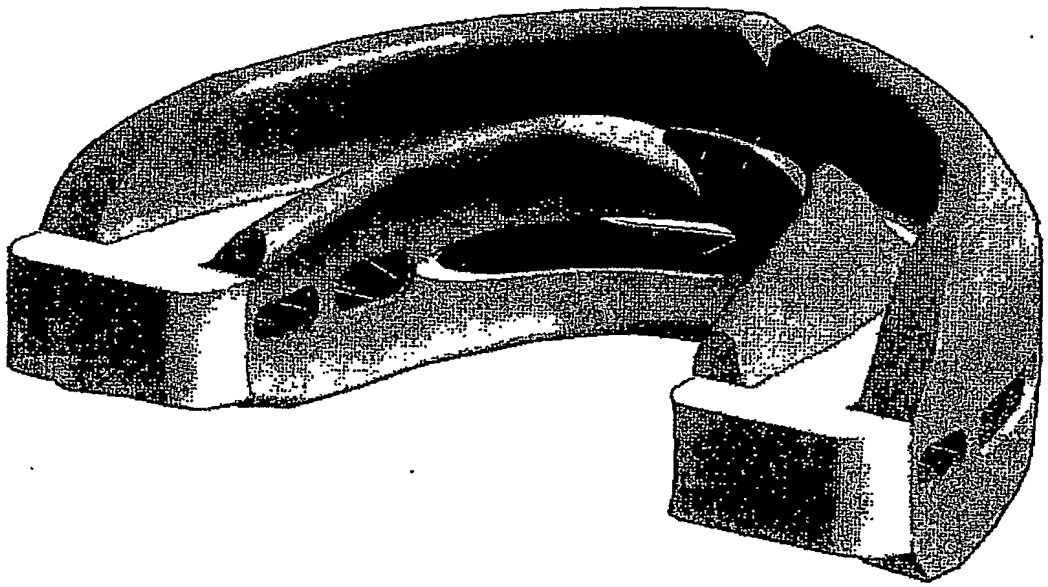
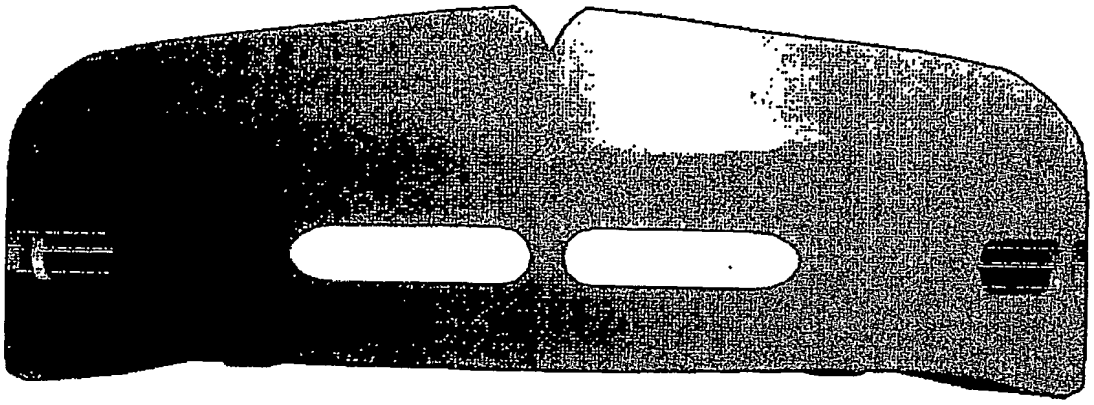


FIG. 22



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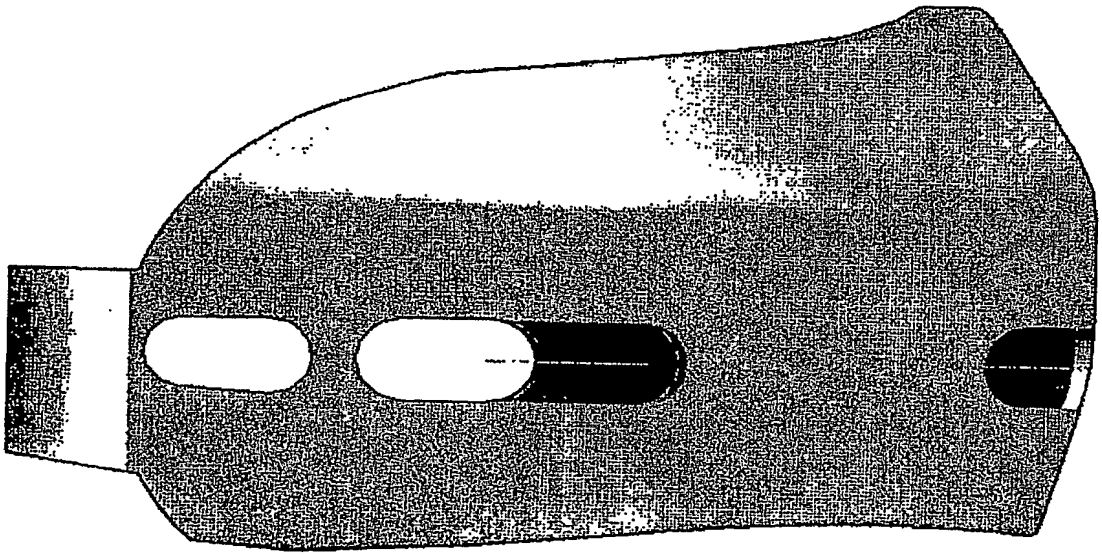


FIG. 24

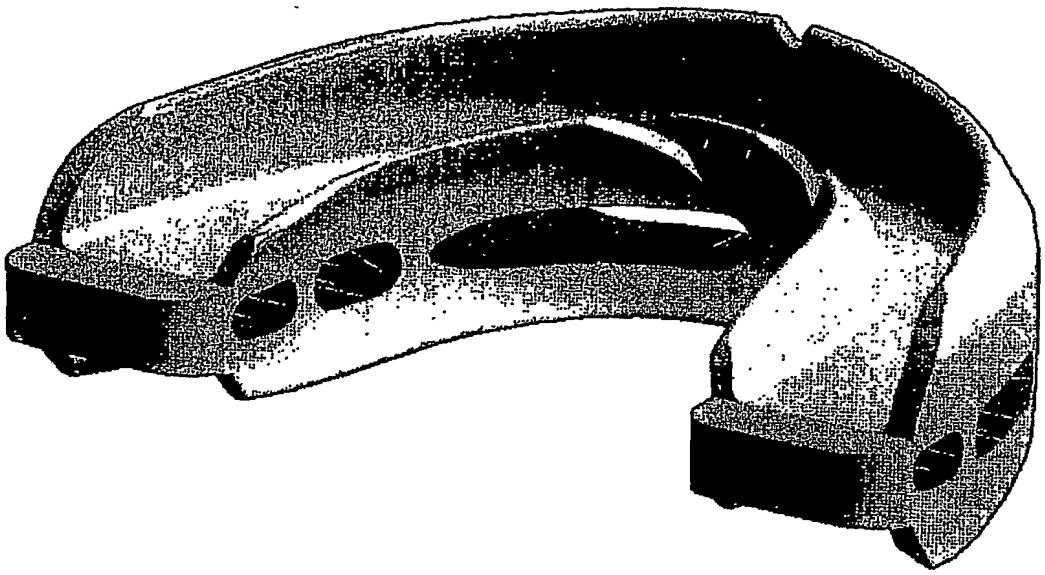
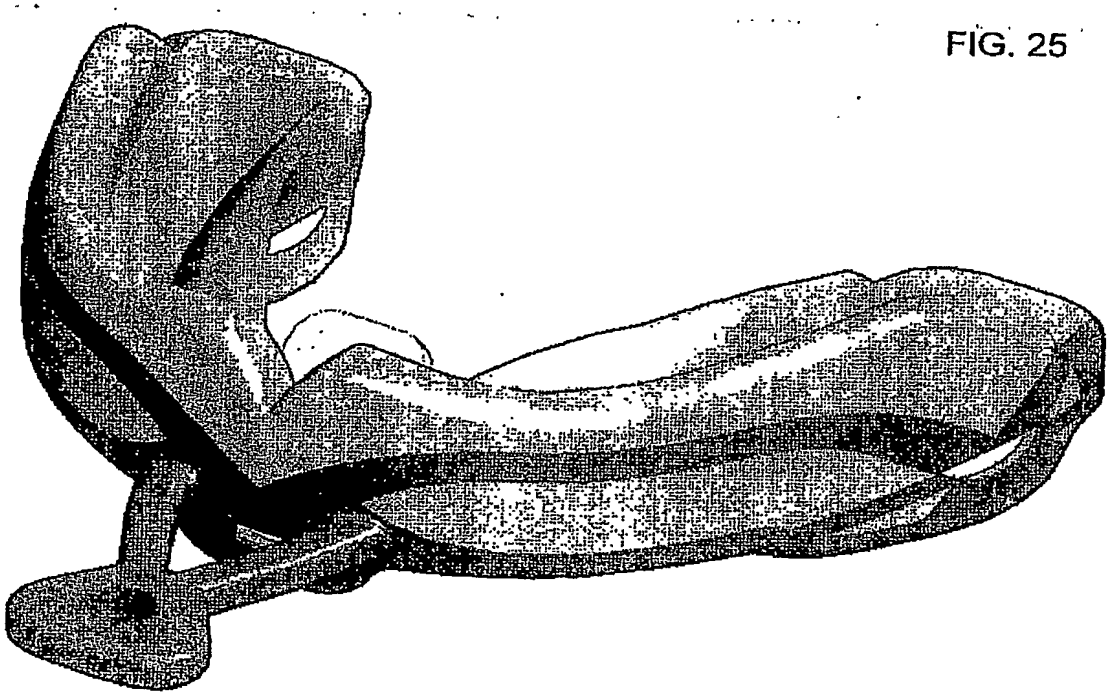


FIG. 25



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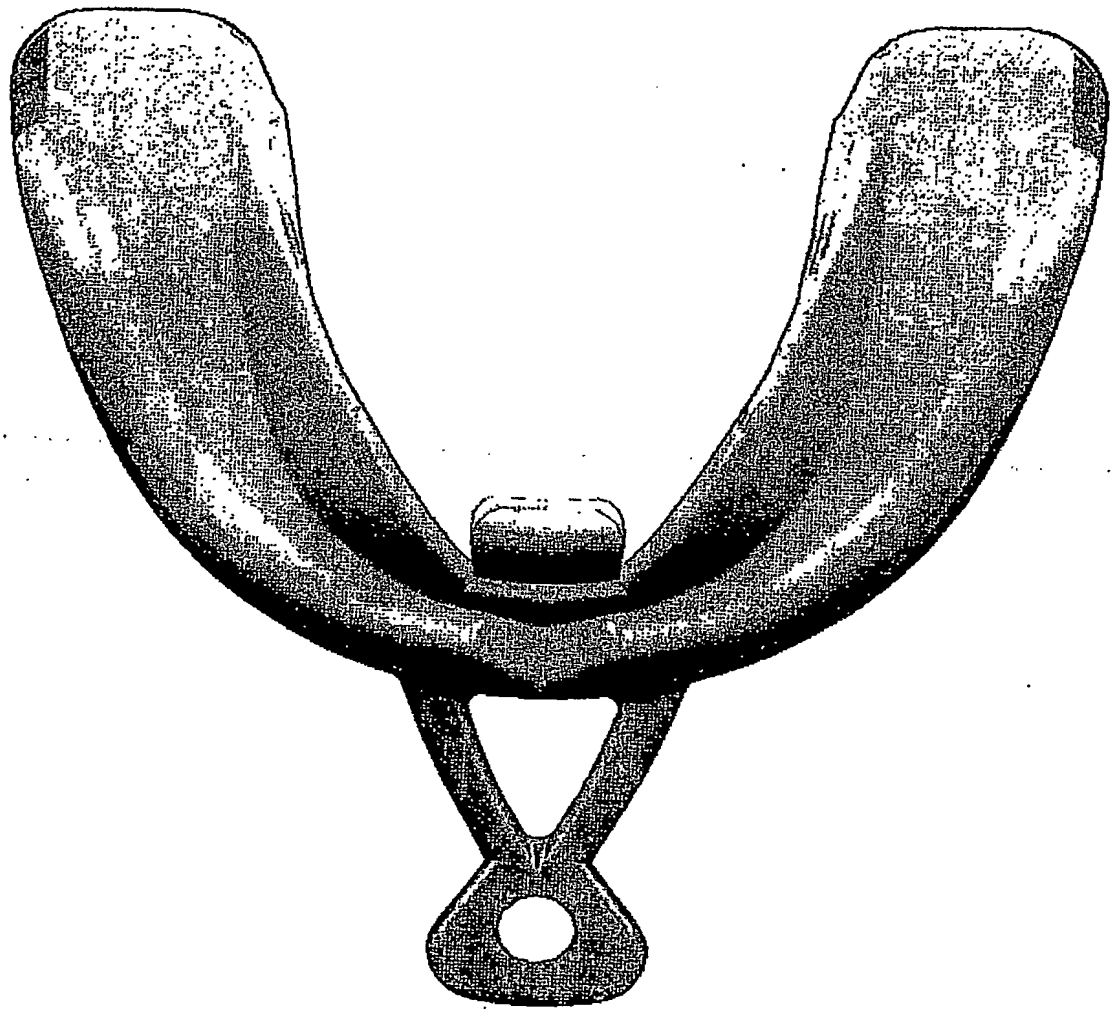

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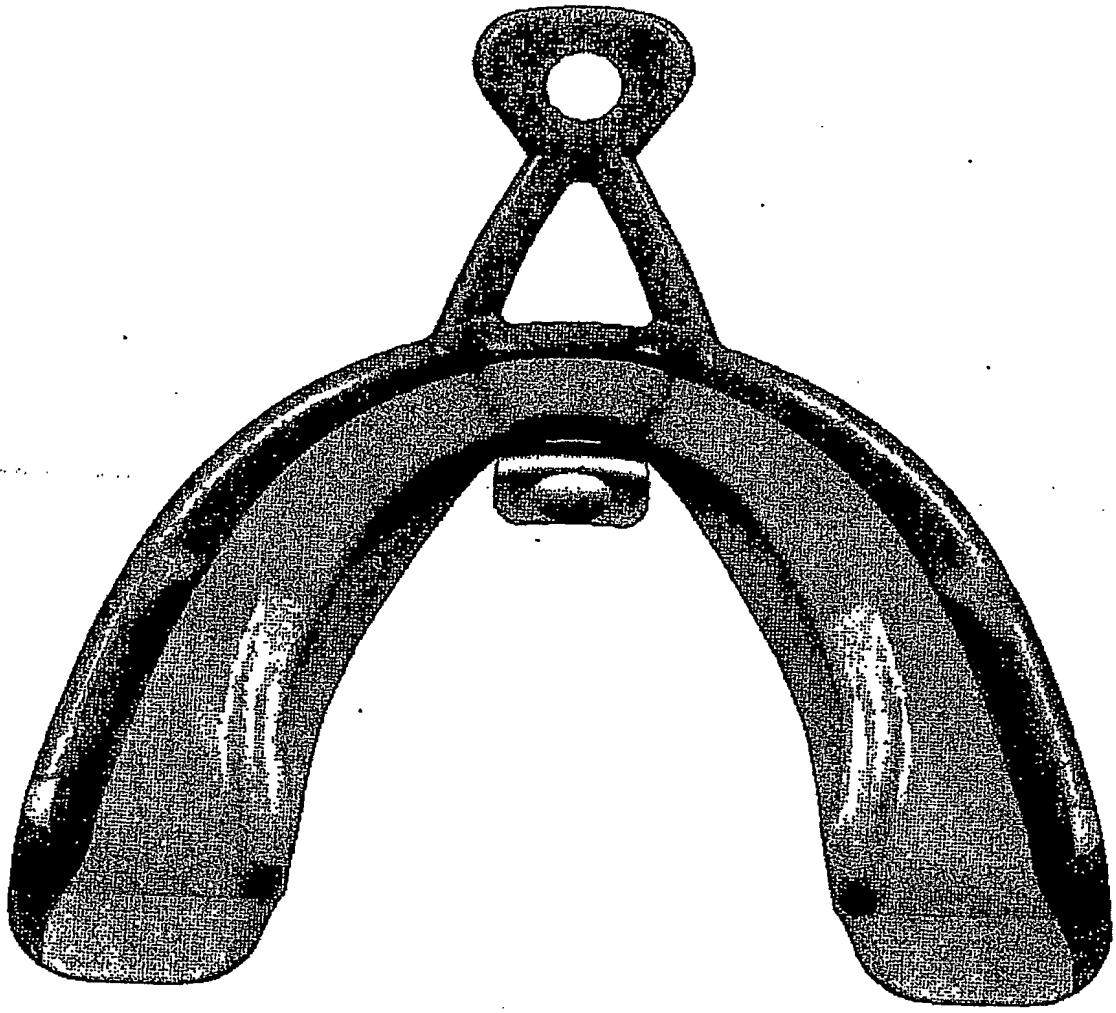


FIG. 28

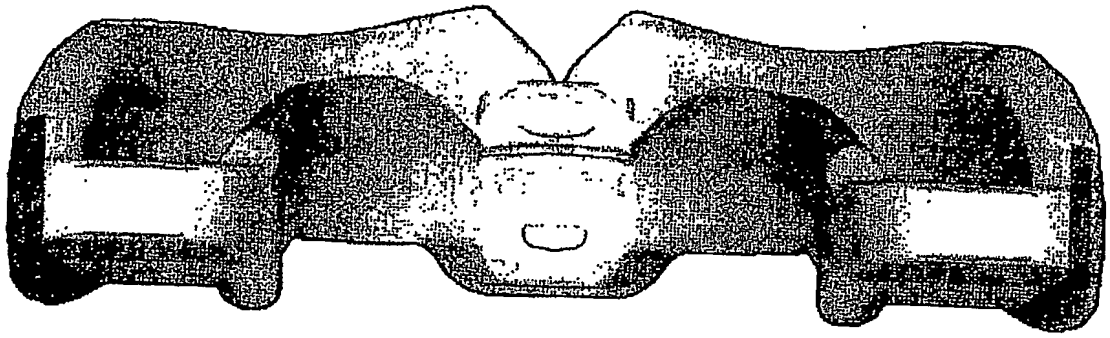


FIG. 29

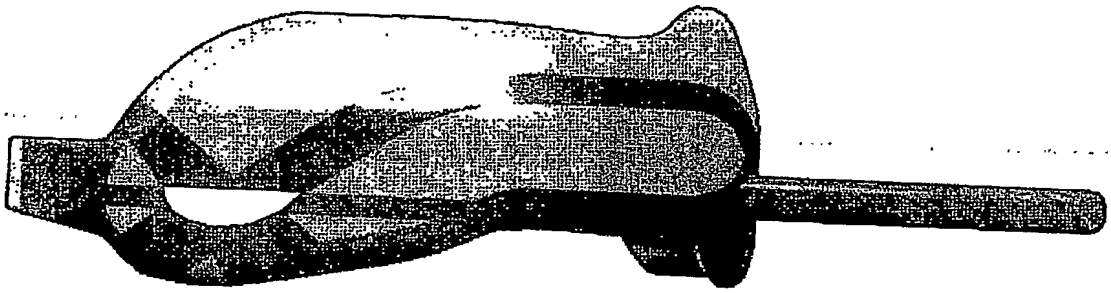
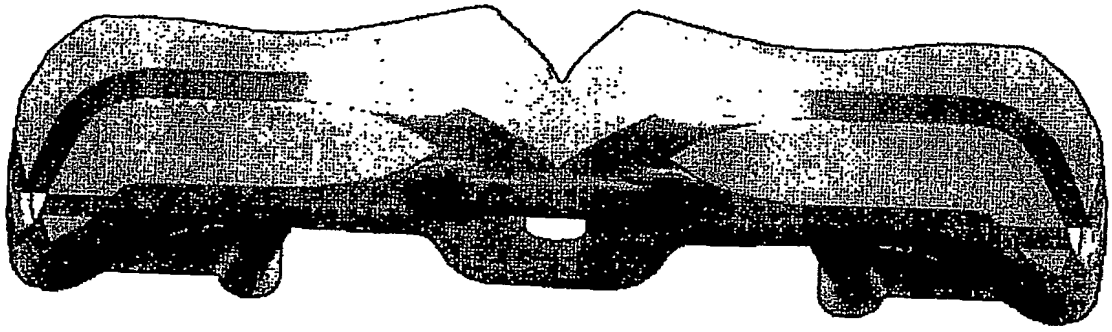


FIG. 30



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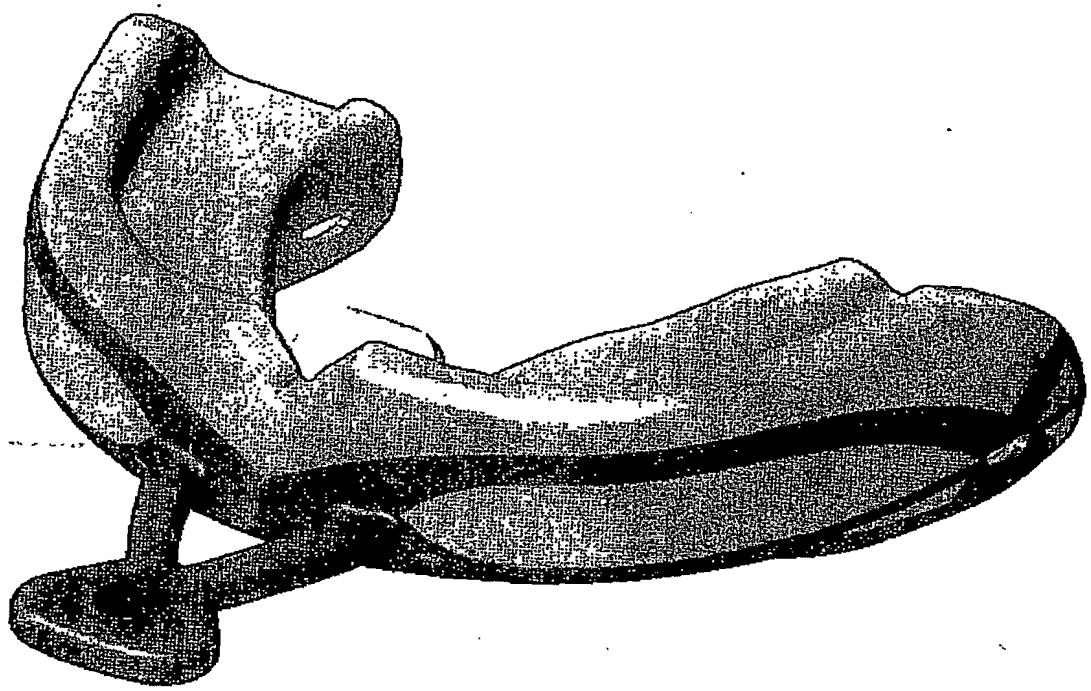

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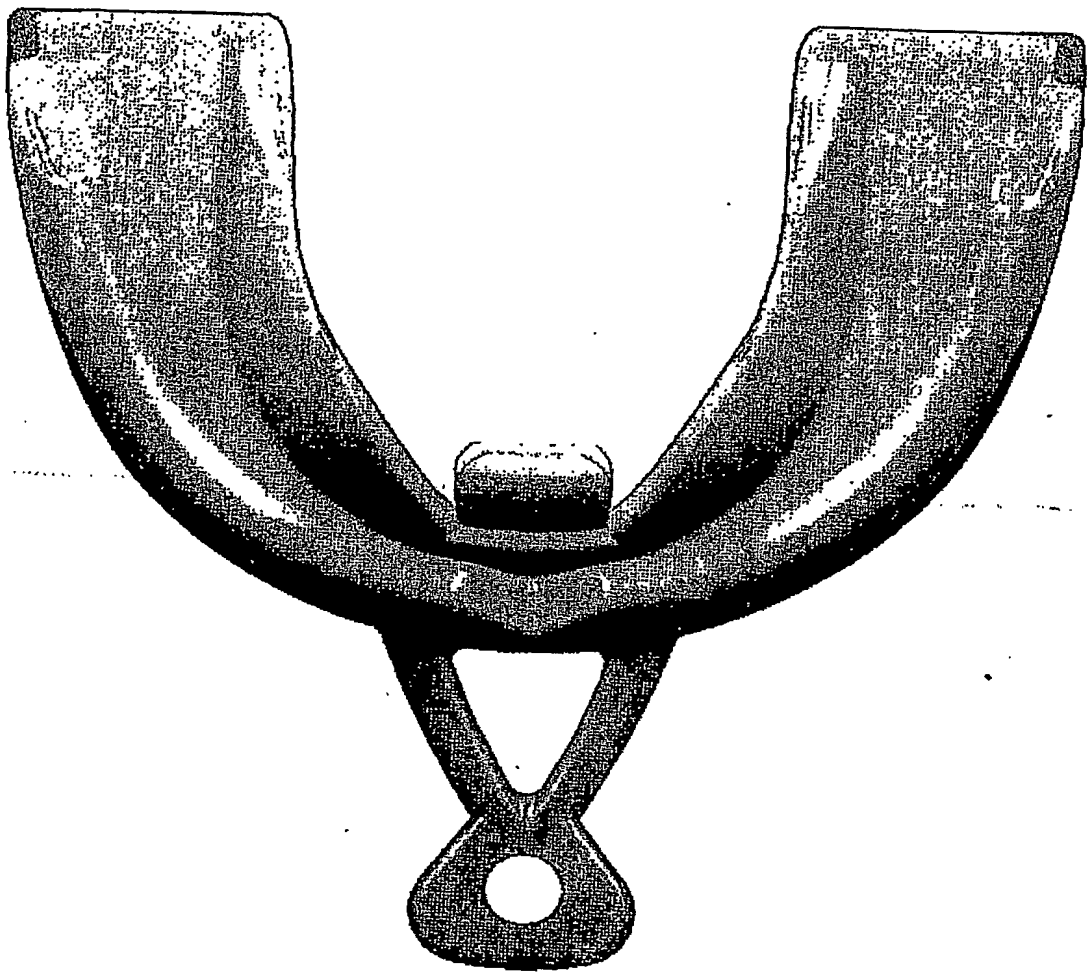

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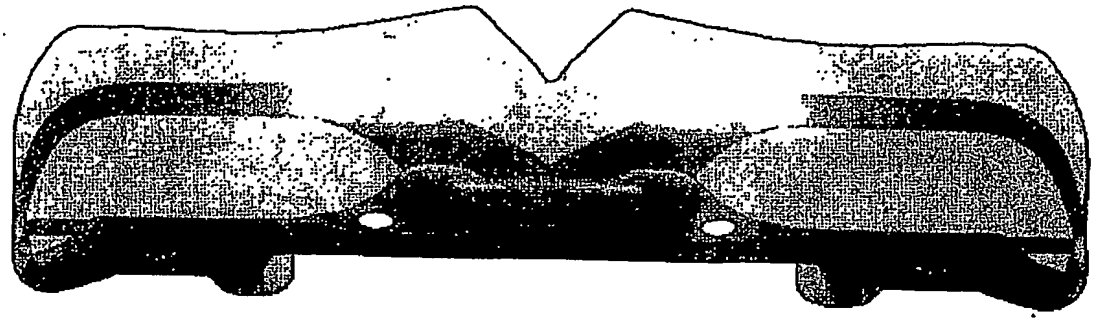

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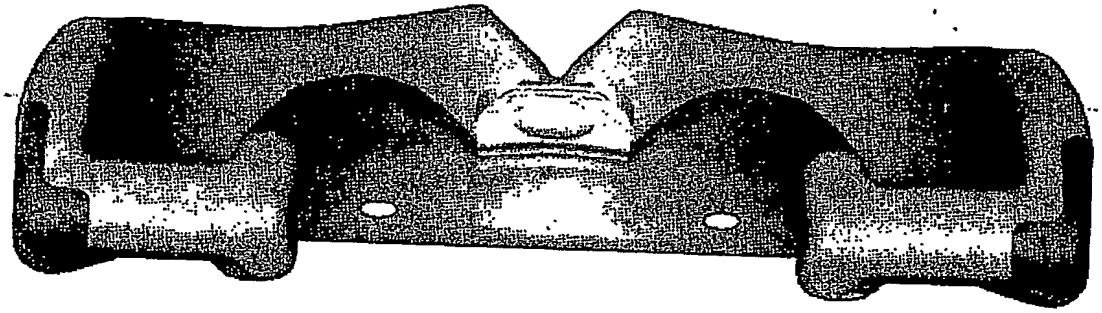

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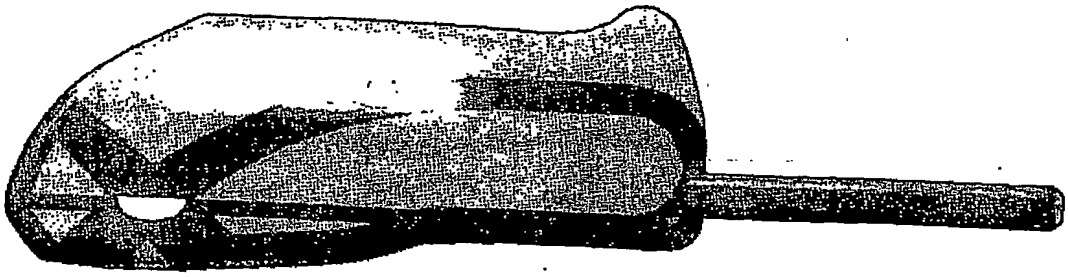

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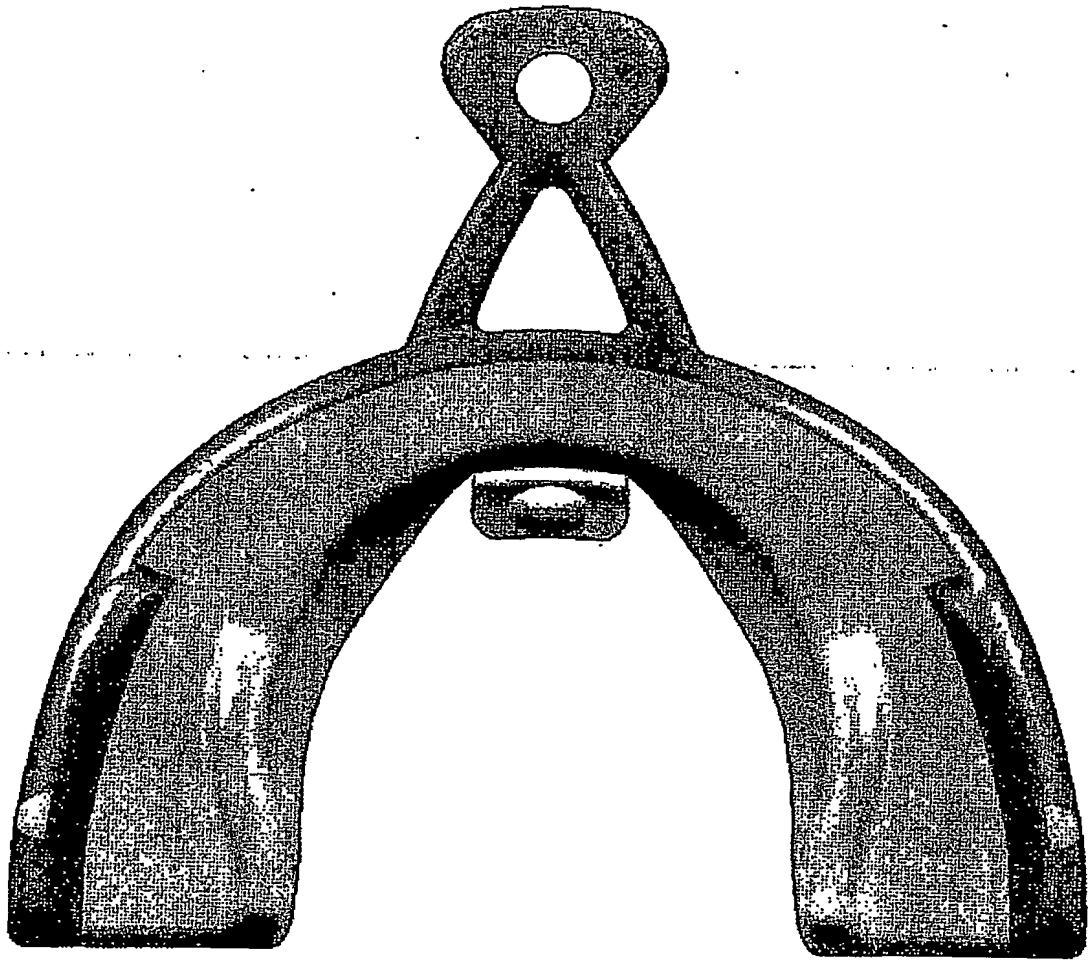

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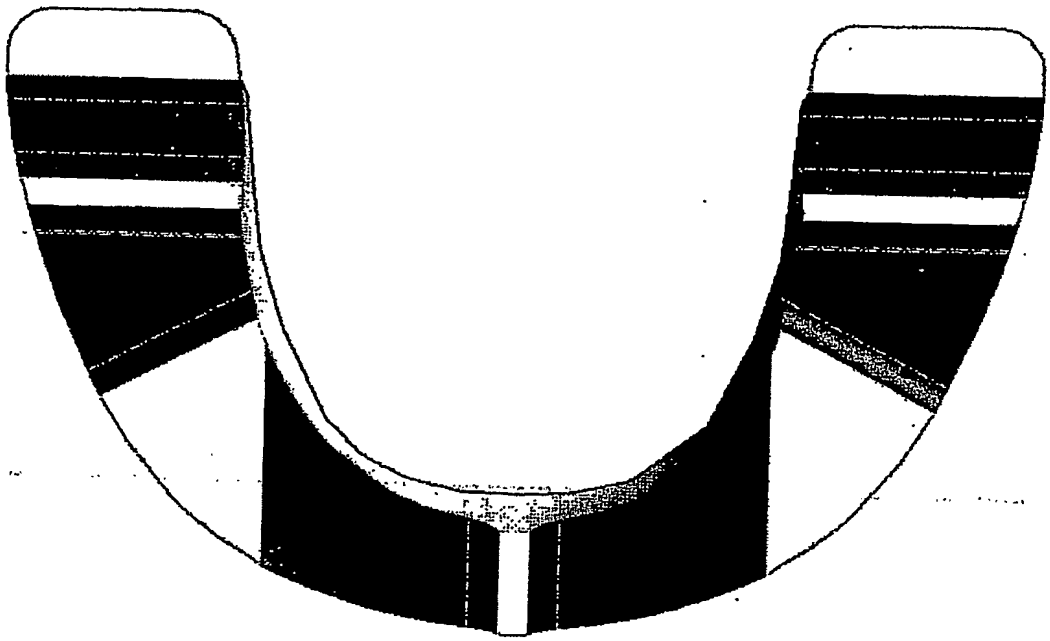

FIG. 38

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